

EPA REGISTRATION NUMBER 264-1125

ISB'S Front-end PRIA Completeness Screen

Draft 3; 10/25/07

EPA Receipt Date: APR - 2 2010		EPA Reg. Number: 264- RREL		
	Check List Item	Yes	No	N/A
1	Has the PRIA Fee been Paid ; is a copy of the check or Pay.gov receipt included in the Submission Package?	X		
2	Is an Application Form (EPA Form 8570-1) Included in the Submission Package, is it completely filled out and signed including package type?	X		
3	Is a Confidential Statement of Formula (EPA Form 8570-29) Included in the Submission Package, is it completely filled out and signed (boxes 1-21)?	X		
4	Is a Formulator's Exemption Statement (EPA Form 8570-27) Included in the Submission Package?	X		
5	Is a Certification with Respect to Citation of Data (EPA Form 8570-34) Included in the Submission Package?	X		
6	Is a Data Matrix (EPA Form 8570-35) Included in the Submission Package?	X		
7	Is a Label Included in the Submission Package?	X		
8	Are Data Included in the Submission Package?	X		
9	Is the Submission an Amendment?		X	

Material Sent for Data Extraction

Reg. # 264-1125

Description: CSF Notification per PRN 98-10



Material(s) Sent to Data Extraction Contractors:

☐ New Stamped Label Dated _____

☐ Notification Dated _____



New CSFs Dated 9/26/12, 9/27/12, 9/28/12

☐ Other: _____

☐ Decision #: 473618

☐ Other Action/Comments: _____

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: Julie A. Chao

Phone: 308-8735 Division: RD/IRB

Date: January 15, 2013

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460



OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

January 15, 2013

Dr. Jamin Huang
Bayer CropScience
P.O. Box 12014
2 T.W. Alexander Drive
Research Triangle Park, NC 27709

Subject: Notification of Updated Basic CSF and Alternate CSFs #1 and #2, per PRN 98-10

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10, dated October 31, 2012, for EPA Reg. No. 264-1125, "Emesto Quantum." The Registration Division (RD) has conducted a review of your request for applicability under PRN 98-10, and finds that the actions requested fall within the scope of PRN 98-10.

The CSFs submitted with your application have been stamped "Notification" and placed in our files. Please note that the record for this product currently contains the following CSF:

- Basic CSF (264-1125.B012), dated September 26, 2012
- Alternate CSF #1 (264-1125.A012), dated September 28, 2012
- Alternate CSF #2 (264-1125.A001), dated September 27, 2012

Any previously dated CSFs are superseded. If you have any questions, please contact me directly at 703-308-8735 or email me at chao.julie@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "Julie A. Chao".

Julie A. Chao
Insecticide-Rodenticide Branch
Registration Division (7505P)
Office of Pesticide Programs

Bayer CropScience



October 31, 2012

Document Processing Desk
Office of Pesticide Programs (7505P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, Virginia 22202-4501

ATTENTION: Marianne Lewis (RD, Insecticide-Rodenticide Branch)

**Re: Submission of Updated Confidential Statements of Formula for
Emesto Quantum (EPA Reg. No.: 264-1125)**

Dear Ms. Lewis,

Bayer CropScience is herein submitting updated confidential statements of formula (CSF) based on the previously reviewed and approved CSF to comply with the requirement # 3-a in the May 11, 2012 Notice of Registration for Emesto Quantum. Below is a table to show which updated CSF is corresponding to which previously reviewed and approved CSF by the Agency. No change in content is made in this update.

Bayer CropScience
2 T.W. Alexander Drive
P. O. Box 12014
Research Triangle Park,
NC 27709
Tel: 919 549-2000

CSF reviewed by the Agency		Corresponding updated CSF	
Box A	Date	CSF ID #	Date
Basic	3/21/2011	264-1125.B012	9/26/2012
Alternate 2	3/22/2011	264-1125.A001	9/27/2012
Alternate 1	3/23/2011	264-1125.A012	9/28/2012

Please contact me at jamin.huang@bayer.com or at 919-549-2634 if you have any questions regarding these updated CSF.

Sincerely,

Jamin Huang, Ph.D.
Senior Regulatory Manager

E-SUBMISSION

TM443048-011V



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 264-1125	2. EPA Product Manager Venus Eagle	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Emesto Quantum	PM# Team 01	
5. Name and Address of Applicant (Include ZIP Code) Bayer CropScience P.O. Box 12014, 2 T.W. Alexander Drive Research Triangle Park, NC 27709 <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input checked="" type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

BCS is submitting updated CSFs based on the previously reviewed and approved CSFs to comply with the requirement # 3-a in the 5/11/2012 Notice of Registration for Emesto Quantum. No change in content is made in this update. See cover letter for the detail. This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA. CONTACT: Jamin Huang. jamin.huang@bayer.com

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal	
				<input type="checkbox"/> Plastic	
				<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input type="checkbox"/> Other (Specify) _____	
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	No. per container
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container.		5. Location of Label Directions <input type="checkbox"/>	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Jamin Huang, Ph.D.		Title Senior Regulatory Manager	
		Telephone No. (Include Area Code) (919) 549-2634	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			8. Date Application Received (Stamped)
2. Signature 		3. Title Senior Regulatory Manager	
4. Typed Name Jamin Huang, Ph. D.		5. Date October 31, 2012	

Receipt for Section 3

S: 928702

Resubmission: ☐ Yes ☒ No

Regulatory Type: Product Registration - Section 3

Fee For Service: ☐ Yes ☒ No

Application Type: Notification

Company: 264 BAYER CROSCIENCE LP

V

Risk Manager: Registration Division, Risk Management Team 1

Product #: 264-1125 Product Name: EMESTO QUANTUM

Override#:

Me Too Section3: Me Too Product Name:

Application Date: 31-Oct-2012

OPP Rec'd Date: 21-Dec-2012

Front End Date: 27-Dec-2012

Risk Manager Send Date: 27-Dec-2012

FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Receipt Content	Des
CSF	

Fast Track: ☐ New Ingredient: ☐

View/Edit

Receipt Description:
CSF Notification to update csf(s) previously approved
[e-Submission pkg 3806]

New Ingredient Request Date:

New Ingredient Received Date:

Form A: ☐ Signature Date:

Form B: ☐ Signature Date:

Print Letter

Enter More Information

Tracking

Material Sent for Data Extraction

Reg. # 264-1125

Description: Registration form 5/11/12, label 5/11/12, emails (5/11/12, 4/16/12, 3/29/12, 3/12/12, 2/22/12, acute tox 10/5/11, pc reviews (8/21/11, 7/21/11, 2/15/11), esubmissions 11/3/10, registrant ltrs 10/19/10 & 3/31/10

☒ Material(s) Sent to Data Extraction Contractors:

☒ New Stamped Label Dated 5/11/12

☐ Notification Dated _____

☒ New CSF(s) Dated BASIC 3/21/11, ALT #1 3/23/11

☒ Other: REGISTRATION 5/11/12

ALT #2
3/22/11

☐ Decision #: _____

☐ Other Action/Comments: _____

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: Marianne Lewis

Phone: 308-8043 Division: IRB/RD

Date: 8/7/12



U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs
Registration Division (7505C)
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

EPA Reg. Number:

264-1125

Date of Issuance:

MAY 11 2012

NOTICE OF PESTICIDE:

☒ Registration
☐ Reregistration
(under FIFRA, as amended)

Term of Issuance:

Unconditional

Name of Pesticide Product:

Ernesto Quantum

Name and Address of Registrant (include ZIP Code):

Bayer CropScience LP
2 T.W. Alexander Drive
P.O. Box 12014
Research Triangle Park, NC 27709

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.

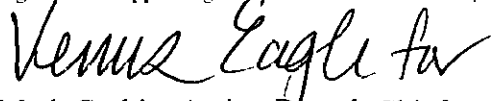
Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is unconditionally registered in accordance with FIFRA section 3(c)(5) provided that you:

1. Submit and/or cite all data required for registration/registration review of your product when the Agency requires all registrant of similar products to submit such data.
2. Make the following label changes before you release the product for shipment:
 - a. Revise the EPA Reg. No. so it reads "EPA Reg. No. 264-1125."
 - b. In the "Commercial Seed Treatment" table in the "Application Rates" column insert "Maximum number of applications per year is 3."
 - c. In the "Commercial Seed Treatment" table in the "Directions" column revise the first two sentences of the dye statement to read as follows: "All seed must be adequately dyed with a suitable colorant to prevent its accidental use as food for man or feed for animals."
 - d. Add the batch code information. Please be reminded that the 40 CFR part 156.140(a)(4) requires a batch code, lot number, or other code identifying the batch of the pesticide product distributed and sold be placed on non-refillable containers. The code may appear either on the label or durably marked on the container itself.
3. For future submissions, make the following changes to your Confidential Statement of Formula (EPA Form 8570-4):
 - a. Box 4: Revise the EPA Reg. No. so it reads "EPA Reg. No. 264-1125."

4. Submit 2 copies of your final printed label before release for shipment.

Signature of Approving Official:



Mark Corbin, Acting Branch Chief
Insecticide-Rodenticide Branch, Registration Division (7505P)

Date:

MAY 11 2012

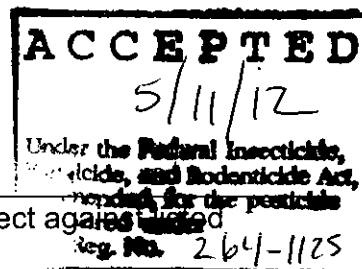
EPA Form 8570-6

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records. If you have any questions, please contact Marianne Lewis at 703-308-8043 or lewis.marianne@epa.gov.

Mark Corbin
Acting Branch Chief,
Insecticide-Rodenticide Branch
Registration Division (7505P)

Enclosure

Emesto Quantum



For use as a fungicide and insecticide cotton seed dressing, designed to protect against disease and insect pests.

ACTIVE INGREDIENT:

Penflufen6.0%
Clothianidin18.6%

OTHER INGREDIENTS:75.4%
TOTAL 100.0%

Contains 1.72 lb Clothianidin and 0.56 lb Penflufen per gallon (206.5 g Clothianidin and 66.6 g Penflufen per liter)

EPA Reg. No. 264-XXXX

EPA Est.

KEEP OUT OF REACH OF CHILDREN CAUTION

For MEDICAL And TRANSPORTATION Emergencies ONLY Call 24 Hours A Day 1-800-334-7577
For PRODUCT USE Information Call 1-866-99BAYER (1-866-992-2937)

FIRST AID

IF SWALLOWED:	<ul style="list-style-type: none">• Call a poison control center or doctor immediately for treatment advice.• Have person sip a glass of water if able to swallow.• Do not induce vomiting unless told to by a poison control center or doctor.• Do not give anything by mouth to an unconscious person.
IF ON SKIN	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15-20 minutes.• Call a poison control center or doctor for treatment advice.
In case of emergency call toll free the Bayer CropScience Emergency Response Telephone No. 1-800-334-7577. Have a product container or label with you when calling a poison control center or doctor, or going for treatment.	

PRECAUTIONARY STATEMENTS

CAUTION

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

Harmful if swallowed. Harmful if absorbed through skin. Avoid contact with skin, eyes or clothing.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Some materials that are chemical-resistant to this product are barrier laminate, butyl rubber, nitrile rubber, neoprene rubber, polyvinyl chloride, or viton. If you want more options, follow the instructions for category C on an EPA chemical-resistance category selection chart.

All mixers, loaders, applicators and other handlers must wear:

- long sleeved shirt and long pants,
- socks plus shoes,
- chemical resistant gloves, except when bagging or sewing bags of treated seeds,

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry.

USER SAFETY RECOMMENDATIONS

Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.

Remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS

This pesticide is highly toxic to bees exposed directly (contact) and is toxic to fish and aquatic invertebrates. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Runoff may be hazardous to aquatic organisms in water adjacent to treated areas. Do not contaminate water when cleaning equipment or disposing of equipment washwater or rinsate. Treated seed exposed on soil surface may be hazardous to wildlife. Cover or collect seed spilled during loading.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

For use only in commercial seed treatment equipment. Not for use in hopper box, planter box, slurry box, or other on-farm seed treatment applications.

COMMERCIAL SEED TREATMENT

CROP	DISEASE AND PEST	APPLICATION RATE	DIRECTIONS
Cotton	Seed rot and damping-off caused by <i>Rhizoctonia solani</i> Thrips (suppression)	Apply 2.31 fl oz per 100 lbs seed (10 g ai per 100 kg seed) To deliver 0.039 mg ai per seed, apply 0.48 fl oz of the product per 100,000 seeds. ¹	Apply using commercial slurry or mist-type seed treatment equipment. Uniform application of seed is necessary to ensure seed safety and best disease protection. Dilute product with sufficient water to ensure complete seed coverage. Use high quality, properly cleaned seed. All seed must be adequately dyed with a colorant. The purchaser of this product is responsible for ensuring that all seed treated with this product are adequately dyed with a suitable color to prevent its accidental use as food for man or feed for animals. Refer to 21CFR, part 2.25. Any colorant added to treated seed must be cleared for use under 40CFR, part 153.155.

¹ Based on 4,800 cottonseed per pound.

SEED BAG TAG

The Federal Seed Act requires that the container of seed treated with Emesto Quantum must be labeled with the following statements:

- This seed has been treated with Emesto Quantum which contains Clothianidin and Penflufen.
- Do not use treated seed for food, feed, or oil production. Excess treated seed may be used for ethanol production only if (1) by-products are not used for livestock feed and (2) no measurable residues of pesticide remain in ethanol by-products that are used in agronomic practice.

In addition, the US Environmental Protection Agency requires the following statements on the container of seed treated with Emesto Quantum:

- User is responsible for ensuring that the seed bag meets all the requirements under the Federal Seed Act.
- Store away from feeds and foodstuffs.
- Wear long sleeved shirt, long pants, shoes, socks, and chemical resistant gloves when handling treated seed
- Immediate Plant-back: Crops for which there are registered uses of both clothianidin and penflufen, which includes canola, cotton, cereal grains except rice, mustard seed, potato (Crop Subgroup 1C) and soybeans may be replanted at any time. Grasses, non-grass livestock feeds, dried beans and dried peas may be planted no less than 30 days after planting treated seeds. Do not plant any other crop in the treated area for at least twelve months after treated seeds are planted.
- After the seeds have been planted, do not enter or allow worker entry into treated areas during the restricted-entry interval (REI) of 12 hours. Exception: Once the seeds are planted in soil or other planting media, the Worker Protection Standard allows worker to enter the treated area without restriction if there will be no worker contact with the treated seeds in the soil or planting media.
- Dispose of all excess treated seed. Left over treated seed may be double sown around the headland or buried away from water sources in accordance with local requirements. Do not contaminate water bodies when disposing of planting equipment washwaters.
- Dispose of seed packaging in accordance with local requirements.
- Use planting equipment that will plant treated seed into the soil to a minimum depth of 0.5 inch.
- This compound is toxic to birds and mammals. Treated seed exposed on soil surface may be hazardous to birds and mammals. Cover or collect seeds spilled during loading.
- Regardless of type of application, do not apply more than 0.2 lbs of the active ingredient clothianidin per acre per season on cotton.
- This compound may be highly toxic to bees exposed directly (contact). Ensure that planting equipment is functioning properly in accordance with manufacturing recommendations to minimize seed coat abrasion during planting to reduce dust which can drift to blooming crops or weeds.
- This product is toxic to fish and aquatic invertebrates. Drift and runoff may be hazardous to aquatic organisms in neighboring areas. Do not apply directly to water or to areas where surface water is present or to intertidal areas below the mean high water mark.
- For cotton: Do not exceed 0.0019 lb. penflufen /A (0.86 g ai/A) per crop season. The maximum number of applications per year is 3. This seed has been treated with xx mg active ingredients (ai) of Emesto Quantum /seed which includes penflufen (10 g ai/100 Kg seed) and clothianidin (31.1 g ai/100 Kg seed)

INFORMATION

EMESTO QUANTUM is a fungicide and insecticide for use on cotton seed designed to protect against listed disease and insect pests.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage, disposal or cleaning of equipment.

PESTICIDE STORAGE

Store in original container away from feed and food. Store in cool, dry area. Do not store in direct sunlight. Do not allow prolonged storage in temperatures that exceed 105°F (40°C) or in temperatures that fall below 14°F (-10°C).

PESTICIDE DISPOSAL

To avoid wastes, use all material in this container by application according to label directions. If wastes cannot be avoided, offer remaining product to a waste facility or pesticide disposal program (often such programs are run by state or local governments or by industry).

CONTAINER DISPOSAL

Rigid, Non-refillable containers equal to or less than 5 gallons)

Non-refillable container. Do not reuse or refill this container. Offer for recycling, if available. Triple rinse or pressure rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container 1/4 full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times.

Pressure rinse as follows: Empty the remaining contents into application equipment or a mix tank and continue to drain for 10 seconds after the flow begins to drip. Hold container upside down over application equipment or mix tank or collect rinsate for later use or disposal. Insert pressure rinsing nozzle in the side of the container, and rinse at about 40 PSI for at least 30 seconds. Drain for 10 seconds after the flow begins to drip.

Once container is rinsed, offer for recycling if available or puncture and dispose of in a sanitary landfill.

Rigid Non-refillable containers greater than 5 gallons or 50 lbs)

Non-refillable Containers

Non-refillable containers - Do not reuse or refill this container. Refer to Bottom Discharge IBC or Top Discharge IBC, Drums, Kegs information as follows.

Bottom Discharge IBC (e.g. - Schuetz Caged IBC or Snyder Square Stackable)

Pressure rinsing the container before final disposal is the responsibility of the person disposing of the container. To pressure rinse the container before final disposal, empty the remaining contents from the IBC into application equipment or mix tank. Raise the bottom of the IBC by 1.5 inches on the side which is opposite of the bottom discharge valve to promote more complete product removal. Completely remove the top lid of the IBC. Use water pressurized to at least 40 PSI to rinse all interior portions. Continuously pump or drain rinsate into application equipment or rinsate collection system while pressure rinsing. Continue pressure rinsing for 2 minutes or until rinsate becomes clear. Replace the lid and close bottom valve.

Top Discharge IBC, Drums, Kegs (e.g. - Snyder 120 Next Gen, Bonar B120, Drums, Kegs).

Triple rinsing the container before final disposal is the responsibility of the person disposing of the container. To triple rinse the container before final disposal, empty the remaining contents from this container into application equipment or mix tank. Fill the container at least 10 percent full with water. Agitate vigorously or recirculate water with the pump for 2 minutes. Rinse all interior surfaces. Pour or pump rinsate into application equipment or rinsate collection system. Repeat this procedure two more times.

Once container is rinsed, offer for recycling if available or puncture and dispose of in a sanitary landfill.

Refillable Containers

Refillable container - Refer to Bottom Discharge IBC or Top Discharge IBC, Drums, Kegs information as follows. Refill this container with pesticide only. Do not reuse this container for any other purpose. Contact your Ag retailer or Bayer CropScience for container return, disposal and recycling information.

Bottom Discharge IBC (e.g. - Schuetz Caged IBC or Snyder Square Stackable)

Pressure rinsing the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. To pressure rinse the container before final disposal, empty the remaining contents from the IBC into application equipment or mix tank. Raise the bottom of the IBC by 1.5 inches on the side which is opposite of the bottom discharge valve to promote more complete product removal. Completely remove the top lid of the IBC. Use water pressurized to at least 40 PSI to rinse all interior portions. Continuously pump or drain rinsate into application equipment or rinsate collection system while pressure rinsing. Continue pressure rinsing for 2 minutes or until rinsate becomes clear. Replace the lid and close bottom valve.

Top Discharge IBC, Drums, Kegs (e.g. - Snyder 120 Next Gen, Bonar B120, Drums, Kegs).

Triple rinsing the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. To triple rinse the containers before final disposal, empty the remaining contents from this container into application equipment or mix tank. Fill the container at least 10 percent full with water. Agitate vigorously or recirculate water with the pump for 2 minutes. Rinse all interior surfaces. Pour or pump rinsate into application equipment or rinsate collection system. Repeat this procedure two more times.

Once container is rinsed, offer for recycling if available or puncture and dispose of in a sanitary landfill.

End users are authorized to remove tamper evident cables as required to remove the product from the container unless the container is equipped with one way valves and refilling or returning is planned. If this is the case, end users are not authorized to remove tamper evident cables, one way valves or clean container.

IMPORTANT: READ BEFORE USE

Read the entire Directions for Use, Conditions, Disclaimer of Warranties and Limitations of Liability before using this product. If terms are not acceptable, return the unopened product container at once.

By using this product, user or buyer accepts the following Conditions, disclaimer of Warranties and Limitations of Liability.

Treatment of highly mechanically damaged seed, or seed of known low vigor and poor quality, may result in reduced germination and/or reduction of seed and seedling vigor. Treat and conduct germination tests on a small portion of seed before committing the total seed lot to a selected chemical treatment. Due to seed quality conditions beyond the control of Bayer CropScience, no claims are made to guarantee germination of carry-over seed.

CONDITIONS: The directions for use of this product are believed to be adequate and must be followed carefully. However, it is impossible to eliminate all risks associated with the use of this product. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as weather conditions, presence of other materials, or the manner of use or application, all of which are beyond the control of Bayer CropScience. All such risks shall be assumed by the user or buyer.

DISCLAIMER OF WARRANTIES: TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BAYER CROPSCIENCE MAKES NO WARRANTIES, EXPRESS OR IMPLIED, OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE OR OTHERWISE, THAT EXTEND BEYOND THE STATEMENTS MADE ON THIS LABEL. No agent of Bayer CropScience is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BAYER CROPSCIENCE DISCLAIMS ANY LIABILITY WHATSOEVER FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT.

LIMITATIONS OF LIABILITY: TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER FOR ANY AND ALL LOSSES, INJURIES OR DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, WHETHER IN CONTRACT, WARRANTY, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE, SHALL NOT EXCEED THE PURCHASE PRICE PAID, OR AT BAYER CROPSCIENCE'S ELECTION, THE REPLACEMENT OF PRODUCT.

NET CONTENTS:

PRODUCED FOR



Bayer CropScience

**Bayer CropScience LP
P.O. Box 12014, 2 T.W. Alexander Drive
Research Triangle Park, North Carolina 27709
1-866-99BAYER (1-866-992-2937)**

EMESTO QUANTUM (PENDING) 03/30/12, 04/02/12, 04/17/12, 05/11/12V2

5/11/12



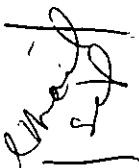
To: Jamin Huang <jamin.huang@bayer.com>,
Cc:
Bcc:
Subject: 264-1125

Jamin,

Revisions for -1125:

✓ p. 2 of environmental hazards revise "This pesticide is toxic to fish and aquatic invertebrates..." to read "This pesticide is highly toxic to bees exposed directly (contact) and is toxic to fish and aquatic invertebrates."

✓ p.2 in the table under "Application Rate" - on all of the other labels it states (x g ai per 100 kg seed) - please add this in here.

 p. 2 in the table under "Directions" - revise the dye info to read "All seed **must be** adequately dyed with a suitable color to" (change in **bold**)

p. 3 under "Seed Bag Tag" in the first section (required by FSA) add this bullet

"User is responsible for ensuring that the seed bag meets all the requirements under the Federal Seed Act."

p. 3 add the "Do not exceed 0.00xx lbs active ingredient/A/per season (0.xx g ai/A/season) . The maximum number of applications per year is xx. This seed has been treated with xx mg ai/seed (xx g ai/100 Kg seed).

Think that is it for this one - some of the above I emailed you about (generally) yesterday.

M

S
4/16/12

Dear Mr. Huang:

Please make the following revisions to your EPA Reg. No. 264-1125 label:

- ✓ 1. On page 2 of the label, for clarity and consistency in the box "Commercial Seed Treatment – Application Rate" delete "Rate per 100 lbs of seed" – this isn't necessary – it's only the one crop and in the next statement you say how much to apply to 100 lbs of seed.
- ✓ 2. On page 2 of the label, for clarity and consistency in the box "Commercial Seed Treatment – Directions" after the last sentence "...properly cleaned seed." add the statement regarding the seed colorant (as per our discussion as to where this dye is added).
3. On page 2 of the label, as per the HED review revise the "Immediate plant back ..." bullet to read as follows:
✓ "Crops for which there are registered uses of both clothianidin and penflufen, which includes canola, cotton, cereal grains except rice, mustard seed, potato (Crop Subgroup 1C) and soybeans may be replanted at any time. Grasses, non-grass livestock feeds, dried beans and dried peas may be planted no less than 30 days after planting treated seeds. Do not plant any other crop in the treated area for at least twelve months after treated seeds are planted."
- ✓ 4. On page 3 of the label, for clarity and consistency remove the bullet "This product does not contain colorant... part 153.155." since this was addressed in #2 above.
5. On page 3 of the label, for clarity and consistency increase the font size of the subheader "Storage and Disposal" to match "Seed Bag Tag."

Please submit these label changes back to me via email (lewis.marianne@epa.gov) as soon as possible so that I can proceed with this action and stamp off on a clean label.

If you have any questions please call or email.

Thanks,

Marianne Lewis
Biologist
IRB/RD 703 308-8043

Dear Mr. Huang:

Please make the following revisions to your EPA Reg. No. 264-1125 label:

- ✓ 1. On page 2 of the label, for clarity and consistency under "Environmental Hazards" revise "...not contaminate water when disposing of equipment washwater..." to read "...not contaminate water when **cleaning equipment or** disposing of equipment washwater..." (changes indicated in **bold**)
2. On page 3 of the label, for clarity and consistency under "Seed Bag Tag" add the following bullet:
 - ✓ - "This product is toxic to fish and aquatic invertebrates. Drift and runoff may be hazardous to aquatic organisms in neighboring areas. Do not apply directly to water or to areas where surface water is present or to intertidal areas below the mean high water mark."

Please submit these label changes back to me via email (lewis.marianne@epa.gov) as soon as possible so that I can proceed with this action and stamp off on a clean label.

If you have any questions please call or email.

Thanks,

Marianne Lewis
Biologist
IRB/RD 703 308-8043

Send
3/29/12

Dear Mr. Huang:

Please make the following revisions to your EPA Reg. No. 264-1125 label:

1. On page 1 of the label, for clarity and consistency under "Hazards to Humans and Domestic Animals revise "...Harmful if absorbed through skin. Avoid contact with skin, eyes, or clothing." to read "Harmful if absorbed through skin. **Harmful if inhaled. Causes moderate eye irritation.** Avoid contact with skin, eyes or clothing. **Avoid breathing spray mist.**" (changes indicated in **bold**)
2. On page 2 of the label, for clarity and consistency under the header "Directions for Use" revise "... for use in hopper box, planter box, slurry box, or other on-farm seed treatment applications except for potato seed pieces." to read "... for use in hopper box, planter box, slurry box, or other on-farm seed treatment applications." (~~deleted~~ "except for potato seed pieces")
3. On page 1 through 6 of the label, for clarity and consistency please make the font sizes flow better. The headers Precautionary Statements and Directions for Use should be the next size down under the KOROC statement (see Label Review Manual for sizes) then the subheaders Hazards, PPE, User Safety Recommends, Environ, Ag box, Commercial Seed Treatment, Seed Bag Tag, Information – these should all be the same size but noticeably smaller than the headers.
4. On page 3 of the label, for consistency and clarity under "Cotton - Directions" delete the "Crop Rotation" subheader and information out of the table – the commercial applicator doesn't need to see this – this should be on the Seed Bag Tag for the planter.
5. On page 4 of the label, for clarity and consistency delete the bullet "Do not use treated seed pieces for food or feed." Not needed since this is only for cotton.
6. On page 4 of the label, for clarity and consistency revise the second to last bullet "...reduce dust which can drift to blooming corps or weeds" to read "...reduce dust which can drift to blooming **crops** or weeds." (change indicated in **bold** – sorry, my spelling mistake)
7. On page 6 of the label, for clarity and consistency in the "Storage and Disposal" box delete the last sentence "See Container Disposal Instructions under Storage and Disposal." This paragraph now resides in the Container Disposal section so it doesn't make sense to say this.

Please submit these label changes back to me via email (lewis.marianne@epa.gov) as soon as possible so that I can proceed with this action and stamp off on a clean label.

If you have any questions please call or email.

Thanks,

check cloth
W/V

Marianne Lewis
Biologist
IRB/RD 703 308-8043

Dear Mr. Huang:

Please make the following revisions to your EPA Reg. No. 264-RREL label:

- ✓ 1. On page 1 of the label, for clarity and consistency revise "...designed to protect against certain disease and insect pests." to read "...designed to protect against **listed** disease and insect pests." (changes indicated in **bold**)
- ✓ 2. On page 1 of the label, revise "EPA Reg. No. 264-XXXX" to read "EPA Reg. No. 264-**1125**" (change indicated in **bold**)
- ✓ 3. On page 1 of the label, for clarity and consistency under "First Aid – If Swallowed" revise "...vomiting unless told to do so by a poison ..." to read "...vomiting unless told to by a poison..." ("do so" was **deleted**)
- ✓ 4. On page 1 of the label, for clarity and consistency under "First Aid – If Inhaled" revise "... breathing, call 911 or an ambulance, ..." to read "breathing, call 911 or ambulance, ..." ("an" was **deleted**)
- ✓ 5. On page 1 of the label, for clarity and consistency under "Hazards to Humans and Domestic Animals" revise "Harmful if swallowed, absorbed through the skin ... and wash before reuse." to read "Harmful if swallowed. **Harmful if absorbed through skin.** Avoid contact with skin, eyes, or clothing." (changes indicated in **bold** – also please note that the Wash thoroughly sentences were removed – these don't belong here)
- ✓ 6. On page 2 of the label, for clarity and consistency under "Personal Protective Equipment" revise "...to this product are barrier laminate, nitrile rubber, neoprene rubber. If you..." to read "...to this product are barrier laminate, **butyl rubber**, nitrile rubber, neoprene rubber, **polyvinyl chloride, or viton**. If you ..." (changes indicated in **bold**)
7. On page 2 of the label, as per the EFED under "Environmental Hazards" revise the existing statements to read as follows:

✓ "This pesticide is toxic to fish and aquatic invertebrates. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Runoff may be hazardous to aquatic organisms in water adjacent to treated areas. Do not contaminate water when disposing of equipment washwater or rinsate. Treated seed exposed on soil surface may be hazardous to wildlife. Cover or collect seed spilled during loading."
- ✓ 8. On page 2 of the label, for clarity and consistency under the header "Directions for Use" revise "Not for direction application to seed in a hopper-box, planter-box, or slurry-box" to read "**For use only in commercial seed treatment equipment. Not for use in hopper box, planter box, slurry box, or other on-farm seed treatment applications except for potato seed pieces.**" (changes indicated in **bold**)

✓ 9. On page 2 of the label, for clarity and consistency under the "Directions for Use" please insert the "Agricultural Use Requirements" box – see EPA Reg. No. 264-1120. This seems to be an on-farm application like -1120 for the potato seed pieces so it would also need the Ag box.

10. On page 3 of the label, for consistency and clarity under "Storage and Disposal – Pesticide Disposal" replace the existing language with the following:

✓ "To avoid wastes, use all material in this container by application according to label directions. If wastes cannot be avoided, offer remaining product to a waste facility or pesticide disposal program (often such programs are run by state or local governments or by industry)."

The previous language was acceptable but the states prefer this language.

✓ 11. On page 2 of the label, for clarity and consistency under "Storage & Disposal - Container Disposal" revise the subheader "Rigid, Non-refillable containers small enough to shake (i.e. with capacities equal to or less..." to read "Rigid, Non-refillable containers (equal to or less ..." ("small enough ..capacities" was **deleted** – not needed).

✓ 12. On page 2 of the label, for clarity and consistency under "Storage & Disposal - Container Disposal" revise the subheader "Rigid, Non-refillable containers that are too large to shake (i.e. with capacities greater than 5 gallons or 50 lbs)" to read "Rigid, Non-refillable containers (greater than 5 gallons or 50 lbs)" ("too large... capacities" was **deleted** – not needed)

check
13. On page 2 of the label, as per Label Review Manual and for clarity and consistency in the "Storage and Disposal" box under subheader "Rigid, Non-refillable containers (equal to or less than 5 gallons)" after the "Triple Rinse" instructions insert instructions how to do a "Pressure Rinse."

✓ 14. On page 2 of the label, for clarity and consistency under "Container Disposal – Rigid, Non-refillable containers equal to or less than 5 gallons)" delete "...or if allowed by State and local authorities by burning. If burned stay out of smoke." This is an acceptable statement but Agency is trying to move away from this practice.

✓ 15. On page 3 of the label, for clarity and consistency please move the "Storage and Disposal" box to the end of the label. Having it in the middle of the "Directions for Use" is confusing. Can you incorporate the "Refillable Containers" information into the "Storage and Disposal" box? I don't understand why it's sitting out all by itself at the end of the label.

✓ 16. On page 3 of the label, for clarity and consistency revise the subheader "Labeling of Treated Seed" to read "Seed Bag Tag" and place the following information under it:

"The Federal Seed Act requires that the container of seed treated with Penclo 273.5FS must be labeled with the following statements:

- This seed has been treated with Penclo 273.5FS which contains Clothianidin and Penflufen.
- Do not use treated seed for food, feed, or oil production. Excess treated seed may be used for ethanol production only if (1) by-products are not used for livestock feed and (2) no measurable residues of pesticide remain in ethanol by-products that are used in agronomic practice.

In addition, the US Environmental Protection Agency requires the following statements on the container of seed treated with Penclo 273.5FS:

- Store away from feeds and foodstuffs.
- Wear long sleeved shirt, long pants, shoes, socks, and chemical resistant gloves when handling treated seed
- Immediate plant back: potatoes (Crop Subgroup 1C), cereal grains (Crop Group 15 & 16). 30-day plant back: grasses, non-grass animal feeds, dried beans and dried peas. Do not plant any other crop in the treated area for at least 12 months after treated seeds are planted.
- After the seeds have been planted, do not enter or allow worker entry into treated areas during the restricted-entry interval (REI) of 12 hours. Exception: Once the seeds are planted in soil or other planting media, the Worker Protection Standard allows worker to enter the treated area without restriction if there will be no worker contact with the treated seeds in the soil or planting media.
- Dispose of all excess treated seed. Left over treated seed may be double sown around the headland or buried away from water sources in accordance with local requirements. Do not contaminate water bodies when disposing of planting equipment washwaters.
- Dispose of seed packaging in accordance with local requirements.
- Use planting equipment that will plant treated seed into the soil to a minimum depth of 0.5 inch.
- This compound is toxic to birds and mammals. Treated seed exposed on soil surface may be hazardous to birds and mammals. Cover or collect seeds spilled during loading.
- Do not use treated seed pieces for food, feed, or fodder.
- Regardless of type of application, do not apply more than 0.2 lbs of the active ingredient clothianidin per acre per season.
- This compound may be highly toxic to bees exposed directly (contact). Ensure that planting equipment is functioning properly in accordance with manufacturing recommendations to minimize seed coat abrasion during planting to reduce dust which can drift to blooming crops or weeds.
- This product does not contain colorant. The purchaser of this product is responsible for ensuring that all seed treated with this product are adequately dyed with a suitable color to prevent its accidental use as food for man or feed for animals. Refer to

21CFR, part 2.25. Any colorant added to treated seed must be cleared for use under 40CFR, part 153.155.”

- ✓ 17. On page 3 of the label, for clarity and consistency revise the subheader “General Information” to read “Information.”
- ✓ 18. On page 4 of the label, put the crop rotation restrictions from page 3 in the “Directions” for both “On Farm Seed Piece Application” and “In-Furrow Application Together with Seed Piece Treatment.”
- ✓ 19. On page 3 of the label, for clarity and consistency delete the subheader “Crop Rotation” and the associated language – this information is on the seed bag tag – and in the potato instructions, so it’s not needed here.
- ✓ 20. On page 3 of the label, for clarity and consistency under the subheader “Information” revise “... pieces designed to protect against certain disease...” to read “... pieces designed to protect against **listed** disease...” (change indicated in **bold**)
21. On page 4 of the label, for clarity and consistency directly above the potato table place the following subheader: “On Farm Seed Piece Application:”
22. On page 4 of the label, for consistency in the “On Farm Seed Piece Application” table under “Potato (seed piece) – Directions” revise “For optimal disease control ..” to read “For disease control...” (“optimal” was deleted)
23. On page 4 of the label, for consistency in the “On Farm Seed Piece Application” table under “Potato (seed piece) – Directions” revise “Apply no more than 2.5 fl oz ...” to read “**Do not apply more** than 2.5 fl oz...” (change indicated in **bold** – this makes the sentence more definitive)
24. On page 4 of the label, for consistency in the “On Farm Seed Piece Application” table under “Potato (seed piece) – Directions” revise “For best control of soilborne black...” to read “**To control** soilborne black...” (change indicated in **bold** – makes sentence more definitive)
25. On page 4 of the label, for clarity and consistency please put the “In-Furrow Application Together with Seed Piece Treatment” table under the “On Farm Seed Piece Application” table – like EPA Reg. No. 1120.
26. On page 4 of the label, for clarity and consistency in the “In-Furrow Application Together with Seed Piece Treatment” table under “Directions” place the restriction “Do not apply more than 0.2 lb of clothianidin per acre per crop season.”
27. On page 4 of the label, for clarity and consistency directly above the Cotton table place the following subheader: “Commercial Seed Treatment.”

28. On page 4 of the label, for clarity and consistency in the "Commercial Seed Treatment" table under "Cotton – Directions" revise "Apply using standard slurry or mist-type ..." to read "Apply using **commercial** slurry or mist-type..." (change indicated in **bold**)

29. On page 4 of the label, for clarity and consistency in the "Commercial Seed Treatment" table under "Cotton – Directions" revise "Product should be diluted with sufficient ... high quality, properly cleaned seed" to read as follows:

"Dilute product with sufficient water to ensure complete seed coverage. Use high quality, properly cleaned seed."

The directions to consult with a seed treatment specialist didn't appear to fit here – looked on other commercial seed labels and didn't see it – so removed it.

30. On page 4 of the label, for clarity and consistency in the "Commercial Seed Treatment" table under "Cotton – Directions" the directions for the colorant are now on the seed bag tag (see #16 above). If you want to retain this here – that's fine but I don't think it's necessary.

31. On pages 2 through 6 of the label, for clarity and consistency please order the label like EPA Reg. No. 264-1120.

Please submit these label changes back to me via email (lewis.marianne@epa.gov) as soon as possible so that I can proceed with this action and stamp off on a clean label.

If you have any questions please call or email.

Thanks,

Marianne Lewis
Biologist
IRB/RD 703 308-8043



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND
POLLUTION PREVENTION

10/05/2011

MEMORANDUM

Subject: Name of Pesticide Product: PENCLO 273.5FS
EPA File Symbol: 264-RREL
DP Barcode: D394518
Decision No.: D431563
Action Code: R010.0
PC Code: 100249 Penflufen
044309 Clothianidin

From: John C. Redden, M.S. *[Signature]*
Inert Ingredient Assessment Branch (IIAB)
Registration Division (7505P)

Through: Pv Shah, PhD. Chief *[Signature]*
Inert Ingredient Assessment Branch (IIAB)
Health Effect Division (7509P)

To: Marianne Lewis, RM Team 01
Insecticide and Rodenticide Branch (IRB)
Registration Division (7505P)

Applicant: Bayer CropScience
P.O. Box 12014, 2 T.W. Alexander Drive
Research Triangle Park, NC 27709

<u>Active Ingredient</u>	<u>% by weight</u>
Penflufen.....	6.0%
Clothianidin.....	18.6%
<u>Inert Ingredients</u>	<u>75.4%</u>
	100.0%

ACTION REQUESTED: The Risk Manager requests that IIAB review the acute toxicology studies for the new a.i. petition. The product contains penflufen and clothianidin.

BACKGROUND: The proposed use for PENCLO 273.5FS is for use as a fungicide and insecticide for cotton seed and potato seed piece dressing. The application is designed to protect against disease and insect pests.

COMMENTS AND RECOMMENDATIONS:

1. The six studies have been reviewed and are classified as Acceptable.
2. The acute toxicity profile for (PENCLO 273.5FS 264-RREL), is as follows:

<u>Study</u>	<u>Tox. Cat.</u>	<u>Classification</u>	<u>MRID</u>
Acute oral toxicity	III	Acceptable	MRID 48024602
Acute dermal toxicity	III	Acceptable	MRID 48024603
Acute inhalation toxicity	IV	Acceptable	MRID 48024604
Primary eye irritation	IV	Acceptable	MRID 48024605
Primary dermal irritation	IV	Acceptable	MRID 48024606
Dermal sensitization	Negative	Acceptable	MRID 48024607

3. Based on the toxicity profile above, the following are the precautionary and first aid statements for this product as obtained from the Label Review System:

PRECAUTIONARY STATEMENTS

SIGNAL WORD: CAUTION

Hazards to Humans and Domestic Animals:

Harmful if absorbed through skin. Harmful if swallowed. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco, or using the toilet. Wear long-sleeved shirt and long pants, socks, shoes, and chemical resistant gloves. Remove and wash contaminated clothing before reuse. Wear long-sleeved shirt and long pants, Socks, Shoes, and gloves.

First Aid:

If on skin:

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for treatment advice.

If swallowed:

- Call a poison control center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to by a poison control center or doctor.
- Do not give anything to an unconscious person.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

4. In addition, IIAB noted that the registrant has included additional precautionary statements, information on Personal Protective Equipment (PPE) and User Safety Recommendations. IIAB finds this additional labeling information acceptable.

5. The Basic Formulation CSF dated, 02/23/2010 for the proposed product should also be reviewed and accepted by the TRB Product Chemistry Team.

Reviewer: John C. Redden, M.S.
Risk Manager (EPA): Py Shah, PhD.

Date: 09/30/2011

STUDY TYPE: Acute Oral Toxicity - Rat; OCSPP 870.1100; OECD 425.

TEST MATERIAL: The test item is a composition of the following active ingredients: Penflufen (BYF 14182) at 64.50 g/L (certified by analysis) and Clothianidin (TI-435) at 200.2 g/L (certified by analysis). The test material was administered in tap water by gavage. The administration volume was 10 ml/kg bw. The batch number is 2009-006297.

SYNONYMS: PENCLO 27305FS and clothianidin + penflufen FS 273.5 (207+66.5 g/L); Clothianidin+Penflufen FS 207+66.5 g/L

CITATION: Gillissen, U. (2010) BYF 14182 + Clothianidin FS 66.5+207 g/L: Acute Toxicity in the Rat After Oral Administration. Project Number: M/362454/01/2, AT05725, M/362454/01/2/OCR. Unpublished study prepared by Bayer Schering Pharma AG. 29 p.

SPONSOR: Bayer CropScience
P.O. Box 12014, 2 T.W. Alexander Drive.
Research Triangle Park, NC 27709

EXECUTIVE SUMMARY: In an OECD Guideline No. 423 – the Acute Toxic Class Method (MRID 48024602), 2 groups (3 females per group) of Wistar, rats (strain Hsp Cpb:Wu) from Harlan GmbH, 5960 AD Horst, Netherlands) were given a single oral dose of Penflufen (BYF 14182) at 64.50 g/L (certified by analysis) and Clothianidin (TI-435) at 200.2 g/L (certified by analysis). The test material was administered in tap water by gavage. The administration volume was 10 ml/kg bw. Animals were then observed for 14 days. The rats were 8-12 weeks of age and at the start of the study weighed 169 to 229 grams.

Oral LD₅₀ Females > 2000 mg/kg

Based on the Oral LD₅₀ in females, is classified as EPA Toxicity Category III.

This acute oral study is classified as Acceptable. It does satisfy the guideline requirement for an acute oral study (OCSPP 870.1100; OECD 425) in the rat.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided.

RESULTS and DISCUSSION:

Individual animals were dosed as follows:

Table 1: Dose-Response

Dosing mg/kg bw	No. animals that died or sacrificed due to morbidity	No. of animals with signs of toxicity	No. of animals used per group	Mortality (%)
2000 (1 st)	0	0	3	0
2000 (2 nd)	0	0	3	0

In an OECD - Guideline No. 423 - Acute Toxic Class Method (MRID 48024602), 2 groups (3 females per group) of Wistar rats (strain Hsp Cpb. Wu) from Harlan GmbH, 5960 AD Horst, Netherlands) were given a single oral dose of Penflufen (BYF 14182) at 64.50 g/L (certified by analysis) and Clothianidin (TI-435) at 200.2 g/L (certified by analysis). The test material was administered in tap water by gavage. The administration volume was 10 ml/kg bw. Animals were then observed for 14 days. The rats were 8-12 weeks of age and at the start of the study weighed 169 to 229 grams.

Oral LD₅₀ Females > 2000 mg/kg bw

LD₅₀ Calculation: The LD₅₀ value was estimated according to OECD - Guideline for Testing of Chemicals No. 423 - "Acute Oral Toxicity - Acute Toxic Class Method", adopted December 17, 2001.

A. Mortality: There was no mortality in this study.

B. Body weights: There were no toxicologically significant effects on body weight or body weight gain.

C. Clinical observations: No Clinical signs were observed.

D. Gross Necropsy: The necropsies performed at the end of the study revealed no abnormalities.

E. Reviewer's Conclusions: IIAB agrees with the study author's conclusion that the acute oral LD₅₀ is greater than 2000 mg/kg for females. The substance is classified as EPA Toxicity Category III.

F. Deficiencies: None.

Reviewer: John C. Redden
Risk Manager (EPA): Pv Shah PhD

Date: 10/03/2011

STUDY TYPE: Acute Dermal Toxicity - Rat; OCSPP 870.1200; OECD 402

TEST MATERIAL: The test item is a composition of the following active ingredients: Penflufen (BYF 14182) at 64.50 g/L (certified by analysis) and Clothianidin (TI-435) at 200.2 g/L (certified by analysis). The batch number is 2009-006297.

SYNONYMS: PENCLO 27305FS and clothianidin + penflufen FS 273.5 (207+66.5 g/L); Clothianidin+Penflufen FS 207+66.5 g/L

CITATION: Gillissen, U. (2010) BYF 14182 + Clothianidin FS 66.5+207 g/L - Acute Toxicity in the Rat After Dermal Application. Project Number: M/362456/01/2, AT05726, M/362456/01/2/OCR. Unpublished study prepared by Bayer Schering Pharma AG. 31 p.

SPONSOR: Bayer CropScience
P.O. Box 12014, 2 T.W. Alexander Drive
Research Triangle Park, NC 27709

EXECUTIVE SUMMARY: In an acute dermal toxicity study (MRID 48024603), one group (5/sex) of Wistar rats. The strain of Wistar rats used was HsdCpb:Wu (breeder: Harlan GmbH, 5960 AD Horst, Netherlands. At the start of the study the male rats weighted 284 to 298 grams, while the female rats weighted 241 to 257 grams. Males and females, at dosing, were 9-13 weeks old (approximately). The animals were dermally exposed to (Penflufen (BYF 14182) at 64.50 g/L (certified by analysis) and Clothianidin (TI-435) at 200.2 g/L (certified by analysis). The percentage or amount of body surface area was 30 cm² at doses of 2000 mg/kg bw. The test area was covered with a gauze-layer (6.0 cm x 5.0 cm = 30.0 cm²) of a "Cutiplast® steril" coated with an air-tight "Leukoflex®". The gauze strip was placed on the rat's back and secured in place using "Peha®-Haft" cohesive stretch tape, and additionally covered with a "Lomir biomedical Inc. rat jacket", which was connected with a safety pin to the stretch tape to ensure that the animals could not ingest the test substance. After approximately 24 hours the dressings were removed and the area was rinsed with tepid water using soap and gently patting the area dry. Animals were then observed for 14 days.

Dermal LD₅₀ Males > 2000 mg/kg bw
Dermal LD₅₀ Females > 2000 mg/kg bw
Dermal LD₅₀ Combined > 2000 mg/kg bw

Based on the LD₅₀, is classified as EPA Toxicity Category III.

This acute dermal study is classified Acceptable. It does satisfy the guideline requirement for an acute dermal study (OCSPP 870.1200; OECD 402) in the rat.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided.

RESULTS and DISCUSSION:

Dose (mg/kg bw)	Mortality/Number Tested		
	Males	Females	Combined
2000	0/5	0/5	0/10

Statistics: The dermal LD₅₀ calculation was not necessary as only the limit dose of 2000 mg/kg bw was tested.

A. Mortality: There were no deaths.

B. Body weights: At the start of the study body weights were 284 to 298 grams for males and 241 to 257 grams for females. There were no toxicologically significant effects on body weight or body weight development in males and females.

C. Clinical observations: The following local sign was observed in three male animals: partial encrustation of the test area.

D. Gross Necropsy: The necropsies performed at the end of the study revealed no particular findings.

E. Reviewer's Conclusions: IIAB agrees with the study author's conclusion that the acute dermal LD₅₀ is greater than 2000 mg/kg for both sexes. This compound is classified as classified as EPA Toxicity Category III for acute dermal toxicity.

F. Deficiencies: None.

Reviewer: John C. Redden, M.S.
Risk Manager (EPA): Pv Shah PhD

Date: 10/04/2011

STUDY TYPE: Acute Inhalation Toxicity - Rat; OCSPP 870.1300; OECD 403

TEST MATERIAL: BYF 14182 + clothianidin FS 66.5+207 g/L

SYNONYMS: clothianidin + penflufen FS 273.5 (207+66.5 g/L)

CITATION: Folkerts, A. (2010) BYF 14182 + Clothianidin FS 66.5+207 g/L: Activity ID TXELP058: Acute Inhalation Toxicity in Rats. Project Number: M/362603/01/2, AT05746, T2080842. Unpublished study prepared by Bayer Schering Pharma AG. 76 p.

SPONSOR: Bayer CropScience
P.O. Box 12014, 2 T.W. Alexander Drive
Research Triangle Park, NC 27709

EXECUTIVE SUMMARY: An acute inhalation toxicity study (MRID 48024604) of BYF 14182 + clothianidin FS 66.5+207 g/L on rats was conducted in accordance with OECD Guideline No. 403. One group of rats was nose-only exposed to a mean maximum attainable aerosol concentration of 2748 mg/m³ (2.748 mg/L). The target concentration was 5000 mg/m³ and the liquid aerosol generated with undiluted test substance was respirable to rats. Animals were then observed for 14 days. There was no mortality in this study.

LC₅₀ Males = 2.748 mg/L

LC₅₀ Females = 2.748 mg/L

LC₅₀ Combined = 2.748 mg/L

Based on the LC₅₀, is classified as EPA Toxicity Category IV.

This acute inhalation study is classified as Acceptable. It does satisfy the guideline requirement for an acute inhalation study (OCSPP 870.1300; OECD 403) in the rat.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided.

RESULTS and DISCUSSION:

Nominal Conc. (mg/L)	Gravimetric Conc. (mg/L)	MMAD μm	GSD	Mortality (# dead/total)		
				Males	Females	Combined
21.872	0.8738	3.5	2.23	0/5	0/5	0/5

Analytical Conc. (mg/L):	2.748
Chamber Volume (L):	3.8
Total Airflow (L/min):	15
Temperature ($^{\circ}\text{C}$):	22.8
Relative Humidity (%):	90.8
Time to Equilibrium (min):	1

Test Atmosphere / Chamber Description:

To attain a high and temporally stable concentration of the inhalation atmosphere the test substance was aerosolized undiluted. During the exposure period, the test substance in the reservoir of the nebulizer was exchanged approx. each 60 min. to confirm high constancy of the test atmosphere composition.

The aluminum inhalation chamber has the following dimensions: inner diameter = 14 cm, outer diameter = 35 cm (two-chamber system), height = 25 cm (internal volume = about 3.8 L). The construction of the inhalation chamber is shown schematically in Figure 1. Details of this modular chamber and its validation have been published previously (Pauluhn, 1994).

Test atmosphere concentration:

One group of rats was nose-only exposed to a mean maximum attainable aerosol concentration of 2748 mg/m^3 . The target concentration was 5000 mg/m^3 and the liquid aerosol was generated with undiluted test substance that was respirable to rats.

Particle size determination:

The particle-size distribution was analyzed using a BERNER-TYPE AERAS low pressure Critical orifice cascade impactor (Hauke, Gmunden, Austria). The individual impactor stages had been covered by an aluminium foil and glass fibre filter which were subjected to gravimetric analysis. An adhesive stage coating (silicone spray) was not used. Gravimetric analyses were made using a digital balance after drying for 30 min by 70°C .

Statistics: The LC_{50} was calculated using the performed by computer (PC) according to the method of Rosiello et al. (1977) as modified by Pauluhn (1983).

A. **Mortality**: There were no deaths.

B. **Body weights**: Average body weight of the rats was decreased on day 1.

C. **Clinical observations**: The rats displayed the following transient clinical signs: breathing irregular, piloerection, bradypnea, laboured breathing patterns, motility reduced, limp, miosis, gait high-legged and hypothermia. At post exposure day 4 all rats were without clinical signs.

D. **Gross Necropsy**: Two males had lungs with light colored areas. Two females also had lungs with light colored areas.

E. **Reviewer's Conclusions**: IIAB agrees with the study author regarding the acute inhalation LC₅₀ is classified as EPA Toxicity Category IV.

F. **Deficiencies**: None.

Reviewer: John Redden, M.S. **Date:** 10/04/2011
Risk Manager (EPA): Pv Shah, PhD

STUDY TYPE: Primary Eye Irritation - Rabbit; OCSPP 870.2400; OECD 405;

TEST MATERIAL: The test item is a composition of the following active ingredients: Penflufen (BYF 14182) at 64.50 g/L (certified by analysis) and Clothianidin (TI-435) at 200.2 g/L (certified by analysis). The batch number is 2009-006297.

SYNONYMS: PENCLO 27305FS and clothianidin + penflufen FS 273.5 (207+66.5 g/L); Clothianidin+Penflufen FS 207+66.5 g/L.

CITATION: Gmelin, C. (2010) BYF 14182 + Clothianidin FS 66.5+207 g/L: Acute Eye Irritation on Rabbits. Project Number: M/362457/01/2, AT05732, M/362457/01/2/OCR. Unpublished study prepared by Bayer Schering Pharma AG: 24 p.

SPONSOR: Bayer CropScience
P.O. Box 12014, 2 T.W. Alexander Drive
Research Triangle Park, NC 27709

EXECUTIVE SUMMARY: In a primary eye irritation study (MRID 48024605), 0.1 ml of the pure liquid test substance tested in the rabbit. (PENCLO 27305FS and clothianidin + penflufen FS 273.5 (207+66.5 g/L); Clothianidin+Penflufen FS 207+66.5 g/L) undiluted test material was instilled into the conjunctival sac of one eye (which eye was not reported) of a young adult female albino rabbits (strain CrI:KBL(NZW)BR, Charles River, 88353 KiBlegg, Germany) for 24 hours. The eyes were washed after the 24 hour exposure period. If no irritation indices were observed after 72 h, the study was finished. Irritation was scored by the Draize method. The rabbits weighted 2.4 - 3.1 kg body at the start of the study.

In this study, the formulation was non-irritating and is classified as EPA Toxicity Category IV for primary eye irritation.

This study is classified as Acceptable. It does satisfy the guideline requirement for a primary eye irritation study (OCSPP 870.2400; OECD 405) in the rabbit.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided.

RESULTS and DISCUSSION:

A. Observations:

If no irritation indices were observed after 72 h, the study was finished.

Individual Scores for Ocular Irritation

READING	RABBIT NUMBER	CORNEAL OPACITY	IRITIS	CONJUNCTIVA*		
				Redness	Chemosis	Discharge
1 Hour	1	Not measured	Not measured	Not measured	Not measured	Not measured
	2	Not measured	Not measured	Not measured	Not measured	Not measured
	3	Not measured	Not measured	Not measured	Not measured	Not measured
24 Hours	1	0	0	0	0	Not measured
	2	0	0	2	0	Not measured
	3	0	0	0	1	Not measured
48 Hours	1	0	0	0	0	Not measured
	2	0	0	1	0	Not measured
	3	0	0	0	0	Not measured
72 Hours	1	0	0	0	0	Not measured
	2	0	0	0	0	Not measured
	3	0	0	0	0	Not measured
Day 4	1	n/a	n/a	n/a	n/a	n/a
	2	n/a	n/a	n/a	n/a	n/a
	3	n/a	n/a	n/a	n/a	n/a
Day 7	1	n/a	n/a	n/a	n/a	n/a
	2	n/a	n/a	n/a	n/a	n/a
	3	n/a	n/a	n/a	n/a	n/a

*Score of 2 or more required to be considered "positive."

The incidence of positive effects, severity and reversibility are detailed below:

Time Post Instillation	Incidence of Positive Effects		
	Corneal Opacity	Iritis	Conjunctivitis
1 Hour	Not measured	Not measured	Not measured
24 Hours	0	0	1.33
48 Hours	0	0	0.67
72 Hours	0	0	

Time Post Instillation	Severity of Irritation - Mean Score
------------------------	-------------------------------------

1 Hour	Not measured
24 Hours	1.33
48 Hours	0.67
72 Hours	0

B. Results: in this study, the formulation was non-irritating and is classified as EPA Toxicity Category IV for primary eye irritation. The Maximum Mean Total Score was 1.33, recorded 24 hours after test material instillation.

C. Reviewer's Conclusions: IIAB agrees with the study author's conclusions. PENCLO 27305FS is classified as EPA Toxicity Category IV.

D. Deficiencies: The method used complied with the OECD Guideline for Testing of Chemicals No. 405 "Acute Eye Irritation/Corrosion", adopted April 2002; EEC Directive No. 440/2008 Part B - Method B.5, and the principles of the EPA Health Effects Test Guidelines (OPPTS 870.2400), United States, EPA 712-C-98-195 (1998), with the exception that recognized differences exist between OECD - Guideline 405 and EPA - Guideline OPPTS 870.2400.

Reviewer: John C. Redden, M.S.
Risk Manager (EPA): Pv Shah, PhD.

Date: 10/03/2011

STUDY TYPE: Acute Dermal Irritation - Rat; OCSPP 870.2500; OECD 404

TEST MATERIAL: The test item is a composition of the following active ingredients: Penflufen (BYF 14182) at 64.50 g/L (certified by analysis) and Clothianidin (TI-435) at 200.2 g/L (certified by analysis).

SYNONYMS: PENCLO 27305FS and clothianidin + penflufen FS 273.5 (207+66.5 g/L); Clothianidin+Penflufen FS 207+66.5 g/L

CITATION: Gmelia, C. (2010) BYF 14182 + Clothianidin FS 66.5+207 g/L: Acute Skin Irritation/Corrosion on Rabbits. Project Number: M/362461/01/2, TXELP060, AT05731. Unpublished study prepared by Bayer Schering-Pharma AG. 25 p.

SPONSOR: Bayer CropScience
P.O. Box 12014, 2 T.W. Alexander Drive
Research Triangle Park, NC 27709

EXECUTIVE SUMMARY: In an acute dermal irritation study (MRID 48024606), one group of 3 young adult females albino rabbits (strain Crl:KBL(NZW)BR, Charles River, 88353 Kißlegg, Germany) that weighted 2.8 kg were dermally exposed to 0.5 ml of Penflufen (BYF 14182) at 64.50 g/L (certified by analysis) and Clothianidin (TI-435) at 200.2 g/L (certified by analysis) to a skin area of 2.5 cm by 2.5 cm. The skin of the animal was under a gauze patch. The patch was placed on the dorso-lateral areas of the trunk of each animal and was held in place with non-irritant tape for the duration of the exposure period.

Due to a possible irritant potential of the test substance, in the first step only one animal was used and three test patches were applied successively to this animal. The first patch was removed after three minutes. As no serious skin reactions were observed, the second patch was applied and removed after one hour. At this stage the observations indicated that with respect to animal welfare the exposure can be allowed to extend to four hours, therefore the third patch was applied and removed after four hours and the responses were graded one hour later. The test was completed using two additional animals, exposed for four hours. Based on most recent guidelines the dermal irritation was scored approximately at 1, 24, 48 and 72 hours after patch removal. If no irritation indices were observed after 72 h, the study was finished. If dermal irritation was observed, animals were monitored usually on day 7 and 14 after patch removal until the changes had completely subsided, however for not more than 14 days after application.

Table 1 Summary of Irritating Effects (Score

Animal	Effect	24 h	48 h	72 h	Mean scores	Response	Reversible (days)
1	Erythema (redness) and eschar formation Oedema formation	0 0	0 0	0 0	0 0		na na
2	Erythema (redness) and eschar formation Oedema formation	0 0	0 0	0 0	0 0	0 0	na na
3	Erythema (redness) and eschar formation Oedema formation	0 0	0 0	0 0	0 0	0 0	na na

According to classification criteria for OECD - Guideline for Testing of Chemicals No. 404 BYF 14182 + clothianidin FS 66.5+207 g/L is not an irritant to the skin. There were no systemic intolerance reactions.

Based on the LD₅₀, PENCLO 273.5FS is classified as EPA Toxicity Category IV.

This acute dermal study is classified as Acceptable/Guideline and satisfies the requirement for an acute dermal irritation study (OCSPP 870.2500; OECD 402) in the rat.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided.

RESULTS and DISCUSSION:

In an acute dermal irritation study (MRID 48024606), one group of 3 young adult female albino rabbits of (strain Crl:KBL(NZW)BR, Charles River, 88353 Kißlegg, Germany) that weighted 2.8 kg were dermally exposed to 0.5 ml of Penflufen (BYF 14182) at 64.50 g/L (certified by analysis) and Clothianidin (TI-435) at 200.2 g/L (certified by analysis). The area of exposure was 2.5 cm by 2.5 cm. Application of 0.5 ml of the pure liquid test substance was applied to the skin of the animal under a gauze patch. The patch was placed on the dorso-lateral areas of the trunk of each animal and was held in place with non-irritant tape for the duration of the exposure period.

Due to a possible irritant potential of the test substance, in the first step only one animal was used and three test patches were applied successively to this animal, as described above. The first patch was removed after three minutes. As no serious skin reactions were observed, the second patch was applied and removed after one hour. At this stage the observations indicated that with respect to animal welfare the exposure can be allowed to extend to four hours, therefore the third patch was applied and removed after four hours

and the responses were graded one hour later. The test was completed using two additional animals, exposed for four hours. Based on most recent guidelines the dermal irritation was scored approximately at 1, 24, 48 and 72 hours after patch removal. If no irritation indices were observed after 72 h, the study was finished. If dermal irritation was observed, animals were monitored usually on day 7 and 14 after patch removal until the changes had completely subsided, however for not more than 14 days after application.

Table 1 Summary of Irritating Effects (Score)

Animal	Effect	24 h	48 h	72 h	Mean scores	Response	Reversible (days)
1	Erythema (redness) and eschar formation	0	0	0	0	-	na
	Oedema formation	0	0	0	0	-	na
2	Erythema (redness) and eschar formation	0	0	0	0	0	na
	Oedema formation	0	0	0	0	0	na
3	Erythema (redness) and eschar formation	0	0	0	0	0	na
	Oedema formation	0	0	0	0	0	na

According to classification criteria for OECD - Guideline for Testing of Chemicals No. 404 BYF 14182 + clothianidin FS 66.5+207 g/L is not an irritant to the skin. There were no systemic intolerance reactions.

Based on the skin irritation result 266-RREL is classified as EPA Toxicity Category IV.

A. Body weights: Body weights at the beginning of the study were 2.8 kg. Subsequent animal weights were not done.

B. Clinical observations: No adverse clinical observations were reported.

C. Gross Necropsy: Not required.

D. Reviewer's Conclusions: ILAB agrees with the study author regarding the acute dermal irritation potential of 266-RREL. The compound is classified as EPA Toxicity Category IV.

E. Deficiencies: None.

Reviewer: John C. Redden, M.S.

Date: 10/05/2011

Risk Manager (EPA): P. Shah, PhD

STUDY TYPE: Dermal Sensitization - Guinea Pig; OCSPP 870.2600; OECD 406, 429

TEST MATERIAL: PENCLO 27305FS and clothianidin + penflufen FS 273.5 (207+66.5 g/L); Clothianidin+Penflufen FS 207+66.5 g/L

SYNONYMS: PENCLO 27305FS and clothianidin + penflufen FS 273.5 (207+66.5 g/L); Clothianidin+Penflufen FS 207+66.5 g/L

CITATION: Blanck, M. (2010) BYF 14182 + Clothianidin FS 66.5+207 g/L: Evaluation of Potential Skin Sensitization in the Local Lymph Node Assay in the Mouse. Project Number: M/362273/01/2, SA/09342, LYNX/PSI/N/TXELP078. Unpublished study prepared by Bayer CropScience: 41 p.

SPONSOR: Bayer CropScience

P.O. Box 12014, 2 T.W. Alexander Drive
Research Triangle Park, NC 27709

EXECUTIVE SUMMARY: The aim of this study was to assess the potential of BYF 14182 + CLOTHIANIDIN FS 66.5+207 g/l, an agrochemical formulation containing the active ingredients BYF 14182 (penflufen) at 5.80% w/w and clothianidin (TI-435) at 18.0% w/w (batch Number 2009-006297) to induce skin sensitization using the murine Local Lymph Node Assay (MRID 48024607).

Groups of five female CBA/J mice were treated as follows:

- 1) one control group received only the vehicle (1% Pluronic Acid L92® in water);
- 2) three groups received the test substance at a concentration of 10, 25 or 50% in vehicle, and
- 3) one positive control group received 30% alpha-Hexylcinnamaldehyde (CAS N° 101-86-0; batch N°: MKAA2596) in vehicle.

As the formulation BYF 14182 + CLOTHIANIDIN FS 66.5+207 g/l was found to be non-irritant at 100%, two additional groups of five female mice were treated either with the neat formulation at 100%, or the vehicle alone at the same time and in the same conditions as the other groups above.

The test substances or the vehicle were applied on external surfaces of each ear (25 µL/ear) for three consecutive days (Days 0, 1 and 2) at the appropriate concentrations. On Day 5, the cell proliferation in the draining auricular lymph nodes was measured by incorporation of tritiated thymidine. Stimulation indices were then calculated for each treatment group.

No mortality and no clinical signs were observed during the study. No cutaneous reactions were observed in the vehicle, positive control or treated groups. The mean stimulation index (\pm standard deviation) values for the test substance were 1.7 (± 0.9), 1.4 (± 0.7), 1.8 (± 0.5) and 2.0 (± 0.7) at treatment concentrations of 10, 25, 50 and 100% respectively.

The proliferation index value of the positive control alpha-Hexylcinnamaldehyde was 8.0 (± 3.6) at a treatment concentration of 30%, demonstrating the sensitivity of the test. The formulation BYF 14182 + CLOTHIANIDIN FS 66.5+207 g/l were found to be non-sensitizing in the Local Lymph Node Assay.

Based on the results of this study, is not considered to be a dermal sensitizer.

This study is classified as Acceptable. It does satisfy the guideline requirement for a dermal sensitization study (OCSPP 870.2600; OECD 406, 429) in Local Lymph Node Assay.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided.

I. MATERIALS and METHODS

Radio-Isotope..... [^3H] Thymidine

Test substance

- supplier: Bayer CropScience, Germany
- name: CTD+PFL FS 207+66, 5 G
clothianidin + penflufen FS 273.5
(207+66.5 g/L)
- name used in the study: BYF 14182 + CLOTHIANIDIN FS 66.5+207 g/l
- active ingredients: BYF 14182 (penflufen) at 5.80% w/w
clothianidin (TI-435) at 18.0% w/w
- Synonym: CLOTHIANIDIN + PENFLUFEN
FS 207+66.5 g/l
- batch number: 2009-006297
- Specification N°: 102000022950 - 01
- storage conditions: 25 \pm 5°C
- physical form: beige suspension
- expiry date: August 25, 2010

2. Vehicle and/or positive control:

Positive control substance

- supplier: Sigma-Aldrich, France

- batch number:MKAA2596
- name:alpha-Hexylcinnamaldehyde (HCA)
- CAS N°:101-86-0
- physical form:yellow liquid
- purity:95.9%
- expiry date: November 12, 2014

The vehicle 1% Pluronic Acid L92® was selected to ensure compatibility with the test substance and maximum wetting of the mouse ears with the maximum possibility of skin penetration of the various formulation ingredients.

3. Animal assignment and treatment: Thirty-five female CBA/J mice, a inbred strain, was chosen on the basis of previous studies performed in the testing laboratory, in which the CBA/J strain showed more marked responses than other strains examined. In addition, CBA/J strain meets the requirements by regulatory agencies for LLNA studies. The animals were taken from stock animals. Animals were assigned to the treatment groups without use of a statistical procedure.

4. Dose selection rationale: The test substance was provided by Bayer CropScience Germany). Dosing formulations were prepared by suspending the test substance in 1% Pluronic Acid L92® in water to produce the required dosing concentration (v/v). The concentrations of the dosing solutions were not verified analytically.

II. RESULTS and DISCUSSION:

A. Disintegrations per Minute/Mouse (group means):

Group Number	Test Group Name	Mean Stimulation Index Values (SD)
1	Control in 1% aqueous Pluronic Acid®	-
2	BYF 14182+clothianidin FS 66.5+207 g/L at 10% in 1% aqueous Pluronic Acid®	1.7 (0.9)
3	BYF 14182+clothianidin FS 66.5+207 g/L at 25% in 1% aqueous Pluronic Acid®	1.4 (0.7)
4	BYF 14182+clothianidin FS 66.5+207 g/L at 50% in 1% aqueous Pluronic Acid®	1.8 (0.5)
5	HCA at 30% in 1% aqueous Pluronic Acid®	8.0 (3.6)
6	Control in 1% aqueous Pluronic Acid®	-
7	BYF 14182+clothianidin FS 66.5+207 g/L at 100%	2.0 (0.7)

B. Mortality

No mortality and no clinical signs were observed during the study.

C. Body Weights

Body weights wre similar for all groups.

ACUTE TOX ONE-LINERS

DP BARCODE: D394518

PC CODE(S): 100249 Penflufen 044309 Clothianidin

DATE: 10/05/2011

TEST MATERIAL: PENCLO 27305FS

Study/Species/Lab Study # /Date	MRID	Results	Tox. Cat.	Core Grade
Acute oral toxicity / rat	48024602	LD ₅₀ > 2000 mg/kg (females)	III	A
Acute dermal toxicity / rat	48024603	LD ₅₀ > 2000 mg/kg (males and females)	III	A
Acute inhalation toxicity / rat	48024604	LC ₅₀ = 2.748/L (males and females)	IV	A
Primary eye irritation / rabbit	48024605	Non-irritating	IV	A
Primary dermal irritation / rabbit	48024603	Non-irritant	IV	A
Dermal sensitization / guinea pig	48024607	Negative	----	A

Core Grade Key: A = Acceptable, S = Supplementary, U = Unacceptable, W = Waived

FEE



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

DP BAR CODE NO.: 392282
PC Code(s): 044309,100249
FOOD Use: Yes

FILE SYMBOL NO.: 264-RRELs DECISION NO.: 431563
ACTION CODE: R010
NON-FOOD Use: No

DATE OUT: August 1, 2011

SUBJECT: End Use Product Chemistry Review
Product Name: PENCLO 273.5FS

FROM: Hari Mukhoty
Product Chemistry Team
Technical Review Branch / Registration Division (7505P)

Handwritten signature and date: 8/21/11

TO: Marianne Lewis / Venus Eagle PM - 01
Insecticide-Rodenticide Branch / Registration Division (7505P)

Company Name: Bayer CropScience
Formulation Type: Liquid Suspension

INTRODUCTION:

The Registrant has submitted one year Storage stability (Guideline: 930.6317) and Corrosion characteristics (Guideline: 830.6320) data for the proposed end-use product under EPA File Symbol No. 264-RRELs. The data for the two aforesaid Guidelines were submitted under MRID: 485171-01.

The Penflufen products are under the purview of Global review. The primary review of the product chemistry data was performed by Canada / PMRA. The peer review will be conducted by TRB / EPA and Australia. TRB has reviewed the product chemistry data for the proposed product on 07/21/2011 and has found them to be acceptable, with the exception of one year Storage stability (Guideline: 930.6317) and Corrosion characteristics (Guideline: 830.6320) data

TRB now has been requested to evaluate the acceptability of one year Storage stability and Corrosion characteristics data required for the registration of the aforesaid product.

SUMMARY OF FINDINGS:

1. Name of Active Ingredient(s): Clothianidin (18.6%) and Penflufen (6.0%).
2. The source materials of the active ingredients are registered with the Agency (with the exception of TGAI/MUP Penflufen which is undergoing through the process of registration with the Agency).
3. The CSFs of the proposed products have been filled out completely and correctly. All inert ingredients have been screened by IIAB on 04/08/2011 and have been approved for food use (pre-harvest application to growing crops).
4. All inert ingredients have been screened by IIAB on 02/22/2011 and were approved for food uses.

DP BAR CODE NO.: 392282
PC Code(s): 044309,100249
FOOD Use: Yes

FILE SYMBOL NO.: 264-RRELS DECISION NO.: 431563
ACTION CODE: R010
NON-FOOD Use: No

5. The samples for the one-year ambient storage stability study were packaged in a high density polyethylene (HDPE) container. Samples were evaluated at zero time, four, six, nine and thirteen months for storage stability and corrosion characteristics. The recovery rates of the active ingredients for the aforesaid timeframes for Clothianidin were 18.59% w/w, 18.76% w/w, 18.80% w/w, 18.51% w/w, 18.66% w/w and for Penflufen were 6.02% w/w, 5.94% w/w, 6.01% w/w, 5.89% w/w 5.86% w/w respectively. These fall within the certified limits of Clothiadin (17.5 -19.8% w/w) and (5.40 - 6.60% w/w) of Penflufen. The active ingredients were quantified by HPLC method using UV detector set at 298 nm [MRID: 485171-01].

6. There were no observed effects of the formulation on the containers' integrity or the containers upon the formulation's physical characteristics after twelve months storage in HDPE, at ambient conditions [MRID: 485171-01].

CONCLUSIONS:

1. TRB has reviewed one year Storage stability (Guideline: 930.6317) and Corrosion characteristics (Guideline: 830.6320) data for the proposed end-use product generated from observations made at 0, 4, 6, 9, and 13 month intervals and has found them to be acceptable. The review for the aforesaid guidelines can be located in OPPIN CHEM DOCS.

FEE

DP BAR CODE NO.: 388484
PC Code(s): 100249, 044309
FOOD Use: Yes

FILE SYMBOL NO.: 264-RRELa DECISION NO.: 431563
ACTION CODE: R010.0
NON-FOOD Use: No

DATE OUT: July 20, 2011

SUBJECT: End Use Product Chemistry Review
Product Name: PENCLO 273.5FS

FROM: Hari Mukhoty, Product Chemistry Team
Technical Review Branch / Registration Division (7505P)

TO: Marianne Lewis / Venus Eagle PM - 01
Insecticide-Rodenticide Branch / Registration Division (7505P)

Company Name: Bayer CropScience
Formulation Type: Liquid suspension

INTRODUCTION:

The Registrant has re-submitted one basic CSF (dated: 02/21/2011), two amended CSFs (Alt. # 1 dated 03/23/2011 & Alt. # 2 dated 03/22/2011) as alternate formulations to the aforesaid basic and a proposed product specific label for registration of the aforesaid products under EPA File Symbol No. 264-RRELa.

The product chemistry data for the proposed basic were reviewed previously on 02/15/2011 and were not found to be acceptable because of using (a) multiple sources for inert ingredients in basic formulation and (b) using the term commodity in lieu of name & addresses for sources of the inert ingredients. The aforesaid issues have been corrected in the re-submitted CSFs.

The Penflufen products are under the purview of Global review. The primary review of the product chemistry data was performed by Canada / PMRA. The peer review will be conducted by TRB / EPA and Australia. However, the aforesaid reviews will not contain all the information such as CSFs and the MRIDs for Penflufen products required for EPA registration. This review contains the aforesaid information.

TRB has been requested to evaluate the acceptability of the re-submitted CSFs for the registration of the proposed basic product and alternate formulations.

SUMMARY OF FINDINGS:

1. Name of Active Ingredient(s): Clothianidin (18.6%) and Penflufen (6.0%).
2. The source materials of the active ingredients are registered with the Agency (with the exception of TGAI/MUP Penflufen which is undergoing through the process of registration with the Agency).
3. The CSFs of the proposed products have been filled out completely and correctly. All inert ingredients have been screened by IIAB on 04/08/2011 and have been approved for food use (pre-harvest application to growing crops).
4. Certified limits of the active ingredient of the alternate formulation are same as the basic formulation.

DP BAR CODE NO.: 388484
PC Code(s): 100249, 044309
FOOD Use: Yes

FILE SYMBOL NO.: 264-RRELa DECISION NO.: 431563
ACTION CODE: R010.0
NON-FOOD Use: No

5. Confidential Statement of Formula(s):

[X] Basic - Dated: 02/23/2010 re-submitted - Dated: 03/21/2011

[X] Alternate # 1 - Dated: 02/24/2010 re-submitted: Dated: 03/23/2011
2 - Dated: 03/22/2011

Alternate CSF(s) complies with 40CFR §152.43: [X] Yes [] No

6. Product label

a. Ingredient statement: Nominal concentration of AI listed on CSF(s) concur with product label (PR Notice 91-2)

[X] Yes, if not, explain below:

Metallic equivalent: [] Yes [X] NA;

Soluble arsenic: [] Yes [X] NA

Isomeric ratios: [] Yes [X] NA

Acid equivalent: [] Yes [X] NA

b. Health related sub statements:

Petroleum distillate at > 10%: [] Yes [] No [X] NA

Methanol at > 4%: [] Yes [] No [X] NA

c. Physical chemical hazard statement: Product label requires a statement per 40 CFR §156.78 for: flammability, explosive potential or electric insulator breakdown?

[] Yes [X] No

Is the sub statement in compliance with PR Notice 97-6? [X] YES - Uses the term "Other Ingredients"

, if not, explain below:

d. Label requires an additional Storage and Disposal statement: [] Yes [X] No - from product chemistry point of view; if yes explain below:

Total Release Fogger PR Notice 98-6 (40 CFR 156.78 d): [] Yes [] No [X] NA

Final decision of overall label acceptance will be made by the PM.

DP BAR CODE NO.: 388484
 PC Code(s): 100249, 044309
 FOOD Use: Yes

FILE SYMBOL NO.: 264-RRELa DECISION NO.: 431563
 ACTION CODE: R010.0
 NON-FOOD Use: No

7. Group A: Product Chemistry Data

TRB's determination of the acceptability of the data for the proposed product is listed in the tables below.

Guideline No.	Study Title		Data submitted		TRB's Assessment of Data	MRID Nos. 480246-01
			Yes	No		
830.1550	Product Identity & Composition		X		A	"
830.1600	Description of materials used to produce the product		X		A	"
830.1650	Description of formulation process		X		A	"
830.1670	Discussion on the formation of impurities		X		A	"
830.1700	Preliminary analysis		NA			"
830.1750	Certified limits (158.350)	Standard certified Limits				
		Proposed Limits	X		A	
		Justification for wider limits	X		A	
830.1800	Enforcement analytical method #		X		A	"

A = Acceptance, N = Not Acceptable, G = Data Gap,
 W = Waiver Request, I = In Progress, NA = Not Applicable
 # = HPLC using DAD/UV detected set at 298 nm. Used Ext. standard

DP BAR CODE NO.: 388484
PC Code(s): 100249, 044309
FOOD Use: Yes

FILE SYMBOL NO.: 264-RRELa DECISION NO.: 431563
ACTION CODE: R010.0
NON-FOOD Use: No

8. Group B:

Guideline No.	Study Title	Value or Qualitative Description	TRB's Assessment of Data	MRID Nos. 480246-01
830.6303	Physical State	Liquid suspension	A	"
830.6315	Flammability	Does not contain combustible liquid	A	"
830.6316	Explodability	Does not contain contact explosive	A	"
830.7000	pH	5.15	A	"
830.7300	Density /Relative Density	1.11 gm/ml	A	"

A = Acceptance, N = Not Acceptable, G = Data Gap, W = Waiver request,
NA = Not applicable, I = In progress

CONCLUSIONS:

1. TRB has reviewed the CSFs for the proposed basic (03/21/2011) and alternate formulations (Alt. # 1 dated: 03/23/2011 & Alt. # 2 dated: 03/22/2011) and has found them to be acceptable. The CSFs are attached with this review and can be located OPPIN CHEM DOCS.
2. Product chemistry Group A and Group B data, with the exception of one year storage stability (830.6317) and corrosion characteristics (830.6320) data are satisfied and acceptable.
3. The registrant must generate one year storage stability (830.6317) and corrosion characteristics (830.6320) data on the proposed product. It is required that the observations be made at 0, 3, 6, 9, and 12 month intervals. The results must be submitted to the Agency in electronic and hard copy format.
4. The proposed label was screened as it pertains to the product chemistry requirements. The final review of the proposed label and uses are the purview of the PM team.

FEE

DP BAR CODE NO.: 385552
PC Code(s): 100249, 044309
FOOD Use: Yes

FILE SYMBOL NO.: 264-RREL DECISION NO.: 431563
ACTION CODE: R010.0
NON-FOOD Use: No

DATE OUT: February 14, 2011

SUBJECT: End Use Product Chemistry Review
Product Name: PENCLO 273.5FS

FROM: Hari Mukhoty, Product Chemistry Team
Technical Review Branch / Registration Division (7505P)

TO: Marianne Lewis / Venus Eagle PM - 01
Insecticide-Rodenticide Branch / Registration Division (7505P)

Company Name: Bayer CropScience
Formulation Type: Liquid suspension

INTRODUCTION:

The Registrant has submitted one basic CSF (dated 2/23/2010), an amended CSF (dated 02/24/2010) as an alternate formulation (Alt. # 1) to the aforesaid basic and a proposed product specific label for registration of the aforesaid products under EPA File Symbol No. 264-RREL. The registrant submitted product chemistry data under MRID: 480246-01 to support the registration of the proposed products.

The Penflufen products are under the purview of Global review. The primary review of the product chemistry data was performed by Canada / PMRA. The peer review will be conducted by TRB / EPA and Australia. However, the aforesaid reviews will not contain all the information such as CSFs and the MRIDs for Penflufen products required for EPA registration. This review contains the aforesaid information.

This paragraph deals with the issues for correctly filling out the CSFs of the proposed basic and alternate end-use products. The basic end-use products under the current policy should be produced by one manufacturing plant, should have one registered source per active ingredient and one approved source per inert ingredient used in the formulation [basic formulation must have single, defined composition- 40 CFR § 152.43 (a)]. However, in the alternate formulations multiple production sites can be used within USA. Registered alternate sources of the active ingredients can be used in the alternate formulations. Approved alternate sources (accepted by Inert Branch) for the inert ingredients are also acceptable for the alternate formulations under the current policy.

TRB has been requested to evaluate the product chemistry data required for the registration of the proposed basic product and alternate formulations.

SUMMARY OF FINDINGS:

1. Name of Active Ingredient(s): Clothianidin (18.6%) and Penflufen (6.0%).
2. The source materials of the active ingredients are registered with the Agency (with the exception of TGA/MUP Penflufen which is undergoing through the process of registration with the Agency).
3. The CSFs of the proposed products have been filled out completely but not correctly. Multiple alternate sources of inert ingredients are not acceptable. The use of the term "Commodity" should not be used in lieu of supplier name and address. All inert ingredients have been screened by IIAB on 04/15/2010 and found that one inert ingredient used in the formulation has not been approved by IIAB.
4. Certified limits of the active ingredient of the alternate formulation are same as the basic formulation.

DP BAR CODE NO.: 385552
PC Code(s): 100249, 044309
FOOD Use: Yes

FILE SYMBOL NO.: 264-RREL DECISION NO.: 431563
ACTION CODE: R010.0
NON-FOOD Use: No

4. Confidential Statement of Formula(s):

☒ Basic - Dated: 02/23/2010 resubmitted – Dated: NA

☒ Alternate # - Dated: 02/24/2010

Alternate CSF(s) complies with 40CFR §152.43: ☒ Yes ☐ No

5. Product label

a. Ingredient statement: Nominal concentration of AI listed on CSF(s) concur with product label (PR Notice 91-2)

☒ Yes, if not, explain below:

Metallic equivalent: ☐ Yes ☒ NA;

Soluble arsenic: ☐ Yes ☒ NA

Isomeric ratios: ☐ Yes ☒ NA

b. Health related sub statements:

Petroleum distillate at > 10%: ☐ Yes ☐ No ☒ NA

Methanol at > 4%: ☐ Yes ☐ No ☒ NA

c. Physical chemical hazard statement: Product label requires a statement per 40 CFR §156.78 for: flammability, explosive potential or electric insulator breakdown?

☐ Yes ☒ No

Is the sub statement in compliance with PR Notice 97-6? ☒ YES - Uses the term "Other Ingredients"

, if not, explain below:

d. Label requires an additional Storage and Disposal statement: ☐ Yes ☒ No – from product chemistry point of view; if yes explain below:

Final decision of overall label acceptance will be made by the PM.

DP BAR CODE NO.: 385552
 PC Code(s): 100249, 044309
 FOOD Use: Yes

FILE SYMBOL NO.: 264-RREL DECISION NO.: 431563
 ACTION CODE: R010.0
 NON-FOOD Use: No

6. Group A: Product Chemistry Data

TRB's determination of the acceptability of the data for the proposed product is listed in the tables below.

Guideline No.	Study Title		Data submitted		TRB's Assessment of Data	MRID Nos. 480246-01
			Yes	No		
830.1550	Product Identity & Composition		X		N	"
830.1600	Description of materials used to produce the product		X		A	"
830.1650	Description of formulation process		X		A	"
830.1670	Discussion on the formation of impurities		X		A	"
830.1700	Preliminary analysis		NA			"
830.1750	Certified limits (158.350)	Standard certified Limits				
		Proposed Limits	X		A	
		Justification for wider limits	X		A	
830.1800	Enforcement analytical method		X HPLC using DAD/UV detected set at 298 nm. Used Ext. standard		A	"

A = Acceptance, N = Not Acceptable, G = Data Gap,
 W = Waiver Request, I = In Progress, NA = Not Applicable

DP BAR CODE NO.: 385552
PC Code(s): 100249, 044309
FOOD Use: Yes

FILE SYMBOL NO.: 264-RREL DECISION NO.: 431563
ACTION CODE: R010.0
NON-FOOD Use: No

7. Group B:

Guideline No.	Study Title	Value or Qualitative Description	TRB's Assessment of Data	MRID Nos. 480246-01
830.6303	Physical State	Liquid suspension	A	"
830.6315	Flammability	Does not contain combustible liquid	A	"
830.6316	Explodability	Does not contain contact explosive	A	"
830.7000	pH	5.15	A	"
830.7300	Density /Relative Density	1.11 gm/ml	A	"

A = Acceptance, N = Not Acceptable, G = Data Gap, W = Waiver request,
NA = Not applicable, I = In progress

CONCLUSIONS:

1. TRB has reviewed the basic CSF (dated 02/23/2010) for the proposed end-use product and has found it to be unacceptable because of (a) use of multiple alternate sources of inert ingredients in the formulation (b) use of the term "commodity" in lieu of supplier name and address for inerts (c) one inert ingredient used has not been approved by IIAB. Alternate formulation (CSF dated 02/24/2010) is not acceptable because the basic formulation is not acceptable. The CSF is attached with this review and can be located OPPIN CHEM DOCS.
2. Product chemistry Group A and Group B data, with the exception of one year storage stability (830.6317) and corrosion characteristics (830.6320) data are satisfied and acceptable.
3. The registrant must generate one year storage stability (830.6317) and corrosion characteristics (830.6320) data on the proposed product. It is required that the observations be made at 0, 3, 6, 9, and 12 month intervals. The results must be submitted to the Agency in electronic and hard copy format.
4. The proposed label was screened as it pertains to the product chemistry requirements. The final review of the proposed label and uses are the purview of the PM team.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

April 8, 2010

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

OPP Decision Number: D-431563
EPA File Symbol or Registration Number: 264-RREL
Product Name: PENCLO 273.5FS
EPA Receipt Date: 02-Apr-2010
EPA Company Number: 264
Company Name: BAYER CROPSCIENCE LP

MARGARET CHERNY
BAYER CROPSCIENCE LP
2 T.W. ALEXANDER DRIVE, PO Box 12014
RESEARCH TRIANGLE PARK, NC 27709

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application and certification of payment. If you submitted data with this application, the results of the PRN-86-5 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R010.0

NEW AI;FOOD USE;NO FEE: LINKED TO A PRIA APPLICATION;

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 305-6249.

Sincerely,
Front End Processing Staff
Information Technology & Resources Management Division

A large, stylized handwritten signature in black ink, likely belonging to a staff member of the Information Technology & Resources Management Division.

Fee for Service

{871514}~

This package includes the following

☒ New Registration

☐ Amendment

☒ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: ____

for Division

☐ AD

☐ BPPD

☒ RD

Risk Mgr. 1

Receipt No.

S- 871514

EPA File Symbol/Reg. No.

264-RREL

Pin-Punch Date:

4/2/2010

☐ This item is NOT subject to FFS action.

Action Code:

Requested: R010

Granted: R010.0

Amount Due: \$ 0

Parent/Child Decisions:

264-RRRI / 5871482

☒ Inert Cleared for Intended Use

☐ Uncleared Inert in Product

Reviewer: Venus Eagle Date: 4/8/10

Remarks:

E-SUBMISSION

Receipt for Section 3



S: 871514

Resubmission: ☐ Yes ☒ No

Regulatory Type: Product Registration - Section 3

Fee For Service: ☒ Yes ☐ No

Application Type: New Registration

Billable: ☒ Yes ☐ No

Company: 264 BAYER CROSCIENCE LP



Risk Manager: Registration Division, Risk Management Team 1

Product #: 264-RREL Product Name: PENCLO 273.5FS

Override#:

Me Too Section3: Me Too Product Name:

Application Date: 31-Mar-2010

OPP Rec'd Date: 02-Apr-2010

Front End Date: 05-Apr-2010

Risk Manager Send Date:

FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

E-submission # 1705
Registration of new product, PENCLO 273.5 FS

New Ingredient Request Date:

New Ingredient Received Date:

Form A: ☐ Signature Date:

Form B: ☐ Signature Date:

Print Letter

Enter More Information

Tracking

Receipt Content

Study	
CSF	

View/Edit

E-SUBMISSION

Bayer CropScience



Scientific Affairs
Carleton University, CTTC, Building 29
1125 Colonel By Drive, Suite 3800
Ottawa, Ontario
K1S 5R1

October 20, 2010

Katherine Keppel-Jones
Chemistry Evaluation Section
Compliance, Lab Services and Regional Operations Directorate
Pest Management Regulatory Agency
2720 Riverside Drive
Ottawa, Ontario K1A 0K9

Dear Ms. Keppel-Jones:

Re: Penflufen TC, Sub. No. 2010-1288; Response to chemistry clarifications

Please find enclosed Bayer CropScience's response to the product chemistry questions for Penflufen TC (Sub. No. 2010-1288) identified in your e-mail correspondence of September 7, 2010.

If you have any questions or require additional information, please do not hesitate to contact me.

Sincerely,

Jeff Parsons
Registration Manager, Fungicides
Tel. (613) 722-8111, ext 234
Fax (613) 722-1407
Cel: (613) 290-9337
e-mail: jeff.parsons@bayercropscience.com

Bayer CropScience



October 23, 2010

Document Processing Desk
Office of Pesticide Programs (7505P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, Virginia 22202-4501

ATTENTION: Marianne Lewis (RD, Insecticide-Rodenticide Branch)

**Re: Penflufen TC (EPA File Symbol: 264-RRRI)
PEN 240FS (EPA File Symbol: 264-RRRO)
PENRED 240FS (EPA File Symbol: 264-RREN)
PENPRO 118FS (EPA File Symbol: 264-RREG)
PENTRI 308FS (EPA File Symbol: 264-RREU)
PENCLO 273.5FS (EPA File Symbol: 264-RREL)
PENPROME 177FS (EPA File Symbol: 264-RREE)
PENPROTRIME 310.68FS (EPA File Symbol: 264-RRER)**

**Submission of Responses from BCS Canada to the PMRA Completeness
Check**

Bayer CropScience
2 T.W. Alexander Drive
P. O. Box 12014
Research Triangle Park,
NC 27709
Tel: 919 549-2000

Dear Ms. Lewis,

BCS Canada recently submitted *via* e-Index its responses to questions from the Canadian PMRA's Completeness Check regarding product chemistry. We grouped all of the responses into several reports and formatted them per the PRN 86-5 guidelines, and are herein submitting these reports, as listed in transmittal document, to the Agency. All of the cover letters from BCS Canada to PMRA are attached. We will amend our proposed CSF for any of the above-listed products in the US based on the Agency's review.

Please let me know at jamin.huang@bayer.com or at 919-549-2634 if you have any questions.

Sincerely,

Jamin Huang, Ph.D.
Senior Regulatory Manager



M-392572-01-1

ESUBMISSION
62



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

November 2, 2010

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MARGARET CHERNY
BAYER CROPSCIENCE LP
2 T.W. ALEXANDER DRIVE, PO Box 12014
RESEARCH TRIANGLE PARK, NC 27709

PRODUCT NAME: PENCLO 273.5FS
COMPANY NAME: BAYER CROPSCIENCE LP
OPP IDENTIFICATION NUMBER:
EPA FILE SYMBOL: 264-RREL
EPA RECEIPT DATE: 10/26/10

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application appears to qualify for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability for fast track status.

If you have any questions, please contact Registration Division, Risk Management Team 1, at (703) 308-8045.

Sincerely,

P. K. Moore

Front End Processing Staff
Information Services Branch
Information Technology & Resources Management Division

Receipt for Section 3

S: 884780

Regulatory Type: Product Registration - Section 3

Application Type: Pending Product Amendment

Company: 264 BAYER CROPSCIENCE LP

Risk Manager: Registration Division, Risk Management Team 1

Product #: 264-RREL

Product Name: PENCLO 273.5FS

Override#:

Me Too Section3:

Me Too Product Name:

Application Date: 23-Oct-2010

Front End Date: 29-Oct-2010

FFS Due Date:

OPP Target Date:

Fast Track:

Receipt Description: Associated with e-Submission package #2012. Responses to EPA questions

Form A:

Signature Date:

Resubmission: No

Fee For Service: No

Billable: No

V

OPP Rec'd Date: 26-Oct-2010

Risk Manager Send Date: 02-Nov-2010

Negotiated Due Date:

New Ingredient:

Request Date:

New Ingredient:

Received Date:

Signature Date:

Signature Date:

Print Letter

Enter More Information

Tracking

Receipt Content

Des

Study

View/Edit

linked

Fee for Service

{884780<~

This package includes the following

- ☐ New Registration
- ☒ Amendment

☒ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: ____

for Division

- ☐ AD
- ☐ BPPD
- ☒ RD

Risk Mgr. 1

Receipt No.

S- 884780

EPA File Symbol/Reg. No.

264-RREL

Pin-Punch Date:

10/26/2010

☒ This item is NOT subject to FFS action.

Action Code:

Requested:

Granted:

Amount Due: \$ _____

Parent/Child Decisions:

☐ Inert Cleared for Intended Use

☐ Uncleared Inert in Product

Reviewer: 

Date: 11-2-10

Remarks:

ASUBMISSION

FAST-TRACK AMENDMENTS-Completeness Screening Checklist

Experts In-Processing Signature: Steve Schmitz 11/3/10EPA Reg. Number: 264-RREL, etc.EPA Receipt Date: 2-Sub

	Check List Item	Yes	No	NA
1	Application Form (EPA Form 8570-1) - signed?			✓
2	Confidential Statement of Formula (EPA Form 8570-29) - signed?			✓
3	Certification with Respect to Citation of Data (EPA Form 8570-34) signed?			✓
4	Formulator's Exemption Statement (EPA Form 8570-27) - signed?			✓
5	Data Matrix (EPA Form 8570-35) [Applicable, for adding me-too uses]			
	a) Selective Method?			
	b) Cite-All Method? Applicant owns data or list only the companies offered to pay			
	c) Public copy of Matrix provided? See PR Notice 98-5			
6	Is Label Included? (5 copies)			✓
	Comments:			
	2-submissions - Bayer Crop Science Canada responses to PMRA Completeness check			

Bayer CropScience



Scientific Affairs
Carleton University, CTTC, Building 29
1125 Colonel By Drive, Suite 3800
Ottawa, Ontario
K1S 5R1

October 19, 2010

Katherine Keppel-Jones
Chemistry Evaluation Section
Compliance, Lab Services and Regional Operations Directorate
Pest Management Regulatory Agency
2720 Riverside Drive
Ottawa, Ontario K1A 0K9

Dear Ms. Keppel-Jones:

Re: PENCLO 273.5FS, Sub. No. 2010-1278; Response to chemistry clarifications

Please find enclosed Bayer CropScience's response to the product chemistry questions for PENCLO 273.4FS (Sub. No. 2010-1278) identified in your e-mail correspondence of September 7, 2010.

If you have any questions or require additional information, please do not hesitate to contact me.

Sincerely,

Jeff Parsons
Registration Manager, Fungicides
Tel. (613) 722-8111, ext 234
Fax (613) 722-1407
Cel: (613) 290-9337
e-mail: jeff.parsons@bayercropscience.com

Bayer CropScience



Scientific Affairs
Carleton University, CTTC, Building 29
1125 Colonel By Drive, Suite 3800
Ottawa, Ontario
K1S 5R1

October 19, 2010

Katherine Keppel-Jones
Chemistry Evaluation Section
Compliance, Lab Services and Regional Operations Directorate
Pest Management Regulatory Agency
2720 Riverside Drive
Ottawa, Ontario K1A 0K9

Dear Ms. Keppel-Jones:

Re: PENPROME 177FS, Sub. No. 2010-1281; Response to chemistry clarifications

Please find enclosed Bayer CropScience's response to the product chemistry questions for PENPROME 177FS (Sub. No. 2010-1281) identified in your e-mail correspondence of September 7, 2010.

If you have any questions or require additional information, please do not hesitate to contact me.

Sincerely,

Jeff Parsons
Registration Manager, Fungicides
Tel. (613) 722-8111, ext 234
Fax (613) 722-1407
Cel: (613) 290-9337
e-mail: jeff.parsons@bayercropscience.com

BIBLIOGRAPHY OF SUBMITTED DATA

Study No.	Study	Guideline No.	EPA MRID No.
830 Series Product Properties			
830.SUPP BCS Response to PMRA			
1	Cosgrove, D.: BCS response to questions received from the PMRA (September 7, 2010) regarding the product chemistry for PENCLO 273.5 FS (Sub. No. 2010-1278); Bayer CropScience, Regina, Canada; Report No.: US0121; Document No.: M-392561-01-1; October 15, 2010; Pages: 19	830.SUPP	48266301



Re: Deficiencies regarding Penclo 273.5FS (264-RREL)

Megan Pletka to: Mel Tolliver

Cc: Dirk Fredrichsdorf, jamin.huang, Sree Nair

04/16/2010 09:53 AM

Hello Gentlemen,

As mentioned yesterday in the attached email, the agency needs 100% composition (CAS #'s, full product name, chemical name, and %w/w of each component) of the two inerts [REDACTED]

[REDACTED] Please pass on any further information and or questions to the product manager for this application (Venus Eagle). Thank you for all of your help and fast responses in this process. Have a great weekend.

Megan Pletka
EPA Contractor
One Potomac Yard
2777 S. Crystal Drive, S6941
Arlington, VA 22202
(703) 305-6471

Mel Tolliver

Megan, Please e-mail the information.

04/15/2010 02:40:58 PM

From: Mel Tolliver <mel.tolliver@bayercropscience.com>
To: Megan Pletka/DC/USEPA/US@EPA
Cc: Dirk Fredrichsdorf <dirk.fredrichsdorf@bayercropscience.com>, jamin.huang@bayercropscience.com, Sree Nair/DC/USEPA/US@EPA
Date: 04/15/2010 02:40 PM
Subject: Re: Deficiencies regarding Penclo 273.5FS (264-RREL)

Megan,

Please e-mail the information.

Mel Tolliver
Registrations - Fungicides and Seed Treatment

Bayer CropScience LP
2 T.W. Alexander Drive, P.O. Box 12014
Research Triangle Park, NC 27709
Phone: 919-549-2631; Fax: 919-549-2545
Cell Phone: 919-270-0532
Email: mel.tolliver@bayercropscience.com

Pletka.Megan@epamail.epa.gov

04/15/2010 01:33 PM

To mel.tolliver@bayercropscience.com, Dirk Fredrichsdorf <dirk.fredrichsdorf@bayercropscience.com>, jamin.huang@bayercropscience.com

cc Nair.Sree@epamail.epa.gov

Subj Deficiencies regarding Penclo 273.5FS (264-RREL)
ect

Hello again,

We have received information back about the inerts for the above mentioned product and we need 100% composition form the manufacturer of the trade name product. This composition should include full product name, chemical name, CAS number, and percentage of each component. I can email you the list of inerts or fax them, however you prefer. Feel free to call or email if you have any questions. Thanks.

Megan Pletka
EPA Contractor
One Potomac Yard
2777 S. Crystal Drive, S6941
Arlington, VA 22202
(703) 305-6471

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For alternate languages please go to <http://bayerdisclaimer.bayerweb.com>



Re: Deficiencies regarding Penclo 273.5FS (264-RREL)

Megan Pletka to: Mel Tolliver

Cc: Dirk Fredrichsdorf, jamin.huang

04/15/2010 02:43 PM

Mel,

The two inerts that need 100% composition are [REDACTED] Let me know if you have any questions. Thank you.

Megan Pletka
EPA Contractor
One Potomac Yard
2777 S. Crystal Drive, S6941
Arlington, VA 22202
(703) 305-6471

Mel Tolliver

Megan, Please e-mail the information.

04/15/2010 02:40:58 PM

From: Mel Tolliver <mel.tolliver@bayercropscience.com>
To: Megan Pletka/DC/USEPA/US@EPA
Cc: Dirk Fredrichsdorf <dirk.fredrichsdorf@bayercropscience.com>, jamin.huang@bayercropscience.com, Sree Nair/DC/USEPA/US@EPA
Date: 04/15/2010 02:40 PM
Subject: Re: Deficiencies regarding Penclo 273.5FS (264-RREL)

Megan,

Please e-mail the information.

Mel Tolliver
Registrations - Fungicides and Seed Treatment

Bayer CropScience LP
2 T.W. Alexander Drive, P.O. Box 12014
Research Triangle Park, NC 27709
Phone: 919-549-2631; Fax: 919-549-2545
Cell Phone: 919-270-0532
Email: mel.tolliver@bayercropscience.com

Pletka.Megan@epamail.epa.gov

04/15/2010 01:33 PM

To mel.tolliver@bayercropscience.com, Dirk Fredrichsdorf <dirk.fredrichsdorf@bayercropscience.com>, jamin.huang@bayercropscience.com

cc Nair.Sree@epamail.epa.gov

Subj Deficiencies regarding Penclo 273.5FS (264-RREL)
ect

Hello again,

We have received information back about the inerts for the above mentioned product and we need 100% composition form the manufacturer of the trade name product. This composition should include full product name, chemical name, CAS number, and percentage of each component. I can email you the list of inerts or fax them, however you prefer. Feel free to call or email if you have any questions. Thanks.

Megan Pletka
EPA Contractor
One Potomac Yard
2777 S. Crystal Drive, S6941
Arlington, VA 22202
(703) 305-6471

The information contained in this e-mail is for the exclusive use of the intended recipient(s) and may be confidential, proprietary, and/or legally privileged. Inadvertent disclosure of this message does not constitute a waiver of any privilege. If you receive this message in error, please do not directly or indirectly use, print, copy, forward, or disclose any part of this message. Please also delete this e-mail and all copies and notify the sender. Thank you.

For alternate languages please go to <http://bayerdisclaimer.bayerweb.com>



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

April 9, 2010

PREVENTION, PESTICIDES AND

OFFICE OF
TOXIC SUBSTANCES

BAYER CROPSCIENCE LP
2 T.W. ALEXANDER DRIVE, PO Box 12014
RESEARCH TRIANGLE PARK, NC 27709

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 02-APR-10. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

Bayer CropScience



March 31, 2010

480246-00

Document Processing Desk (REGFEE)
Office of Pesticide Programs (7505P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, Virginia 22202-4501

Attention: Ms. Venus Eagle (PM 01, RD)

**Re: Registration Application of a New End-Use Product: PENCLO
273.5FS (EPA Reg. No. 264-XXXX) for Cotton Seed Treatment and
Potato Seed Piece Treatment Use**

As Part of the PRIA R010 Action for Penflufen

Bayer CropScience
2 T.W. Alexander Drive
P. O. Box 12014
Research Triangle Park,
NC 27709
Tel: 919 549-2000

Dear Ms. Eagle,

Bayer CropScience is herein submitting a registration application for a new end-use product, **PENCLO 273.5FS**, as part of the PRIA R010 registration application for Penflufen. We request an extension of the decision time for this PRIA action to be in sync with that of the Penflufen application.

PENCLO 273.5FS contains penflufen (66.6 g/L) and clothianidin (206.5 g/L) for cotton seed treatment and potato seed piece treatment use. The proposed uses on cotton and potato for penflufen in PENCLO 273.5FS are supported by the data from the Penflufen registration application.

For clothianidin on cotton *via* seed treatment use, the proposed use rate in PENCLO 273.5FS is lower than its approved rate in AE 1283742 (EPA Reg. No. 264-846, latest EPA approved label dated 08/13/2009). For clothianidin on potato *via* seed piece treatment, the proposed use rate in PENCLO 273.5FS is lower than its rate for the same use in the pending registration application for Sepresto 75WS (EPA File Symbol. 264-RNIR, OPP Decision No.: D-399489, with negotiated PRIA due date of April 1, 2010). We will delete the use of this proposed product on potato if the pending use of Sepresto 75WS on potato is not approved at the time when the Agency receives this registration application.



M-365395-01-1

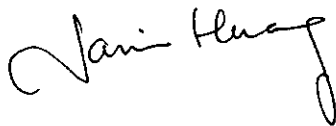
PENCLO 273.5FS is coded as "L1908" or "BYF 14182 + clothianidin FS 66.5+207 g/L", "clothianidin + BYF 14182 FS 207+66.5 g/L" in different reports supporting the registration application of this new product.

In support of this amendment, we are submitting the following:

1. EPA Form 8570-1 dated March 31, 2010
2. A copy of PRIA check for Penflufen \$ 542,115 (PRIA R010)
3. EPA Form 8570-27 dated March 31, 2010
4. EPA Form 8570-34 dated March 31, 2010
5. Data Matrix for PENCLO 273.5FS dated March 31, 2010 (Agency copy)
6. Data Matrix for PENCLO 273.5FS dated March 31, 2010 (Public copy)
7. Proposed labeling for PENCLO 273.5FS dated March 31, 2010
8. Confidential Statements of Formula for PENCLO 273.5FS

Please contact me at 919-549-2634 or at jamin.huang@bayercropscience.com if you have any questions regarding this submission.

Sincerely,



Jamin Huang, Ph.D.
Senior Regulatory Manager

Attachments

Bayer CropScience

April 9, 2010

Document Processing Desk (REGFEE)
Office of Pesticide Programs (7505P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, Virginia 22202-4501

Attention: Ms. Venus Eagle (PM 01, RD)

**Re: Registration Application of a New End-Use Product: PENCLO
273.5FS (EPA File Symbol: 264-RREL) for Cotton Seed Treatment
Use**

As Part of the PRIA R010 Action for Penflufen

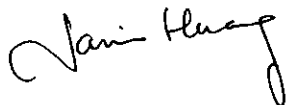
Dear Ms. Eagle,

Per your April 8, 2010 request, Bayer CropScience is submitting an amended draft labeling of **PENCLO 273.5FS** dated April 9, 2010 to the Agency for review as part of the Penflufen registration application.

This labeling has only the proposed seed treatment use on cotton. We removed the previously proposed potato seed-piece use because the pending use of Sepresto 75WS on potato was not approved at the time when the Agency received this registration application.

Please contact me at 919-549-2634 or at jamin.huang@bayercropscience.com if you have any questions regarding this submission.

Sincerely,



Jamin Huang, Ph.D.
Senior Regulatory Manager

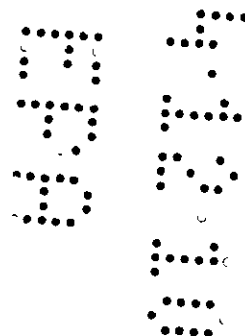
Attachment

*Uploaded to
e-Submission
package 1705
in Documentum.*

4/19/2010



Bayer CropScience
2 T.W. Alexander Drive
P. O. Box 12014
Research Triangle Park,
NC 27709
Tel: 919 549-2000



Bayer CropScience



March 31, 2010

Document Processing Desk (REGFEE)
Office of Pesticide Programs (7505P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, Virginia 22202-4501

Attention: Ms. Venus Eagle (PM 01, RD)

**Re: Registration Application of a New End-Use Product: PENCLO
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Bayer CropScience
2 T.W. Alexander Drive
P. O. Box 12014
Research Triangle Park,
NC 27709
Tel: 919 549-2000

Dear Ms. Eagle,

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PENCLO 273.5FS contains penflufen (66.6 g/L) and clothianidin (206.5 g/L) for cotton seed treatment and potato seed piece treatment use. The proposed uses on cotton and potato for penflufen in PENCLO 273.5FS are supported by the data from the Penflufen registration application.

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M-365395-01-1

E-SUBMISSION

PENCLO 273.5FS is coded as "*L1908*" or "*BYF 14182 + clothianidin FS 66.5+207 g/L*", "*clothianidin + BYF 14182 FS 207+66.5 g/L*" in different reports supporting the registration application of this new product.

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6. Data Matrix for PENCLO 273.5FS dated March 31, 2010 (Public copy)
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8. Confidential Statements of Formula for PENCLO 273.5FS

Please contact me at 919-549-2634 or at jamin.huang@bayercropscience.com if you have any questions regarding this submission.

Sincerely,



Jamin Huang, Ph.D.
Senior Regulatory Manager

Attachments



TRANSMITTAL DOCUMENT

Penflufen

EPA: New Formulation PENCLO 273.5FS

Transmittal Date

March 31, 2010

A handwritten signature in black ink, appearing to read "Jamin Huang".

Company Official:

Company Name:

Bayer CropScience (264)

Company Contact:

Jamin Huang

Company Telephone:

+1 919 549 2634

Bayer CropScience
Crop Protection Division
2 T.W. Alexander Drive
RTP, North Carolina 27709.



M-365812-01-1

Study No.	Study	Guideline No.	EPA MRID No.
830 Series Product Properties Test Guidelines			
1	Hines, D.; Product chemistry of Penclo 273.5FS; Bayer CropScience LP, RTP, NC, USA; Report No.: BR 2691; Document No.: M-365179-01-1; March 01, 2010; Pages: 349	830.1550 830.1600 830.1650 830.1750 830.1800 830.6302 830.6303 830.6317 830.7000 830.7100 830.7300	48024601
870 Health Effects Guidelines			
2	Gillissen, U.; BYF 14182 + clothianidin FS 66.5+207 g/L - Acute toxicity in the rat after oral administration; Bayer Schering Pharma AG, Wuppertal, Germany; Report No.: AT05725; Document No.: M-362454-01-2; February 15, 2010; Pages: 29	870.1100	48024602
3	Gillissen, U.; BYF 14182 + clothianidin FS 66.5+207 g/L - Acute toxicity in the rat after dermal application; Bayer Schering Pharma AG, Wuppertal, Germany; Report No.: AT05726; Document No.: M-362456-01-2; February 15, 2010; Pages: 31	870.1200	48024603
4	Folkerts, A.; BYF 14182 + clothianidin FS 66.5+207 g/L - Activity ID TXELP058 - Acute inhalation toxicity in rats; Bayer Schering Pharma AG, Wuppertal, Germany; Report No.: AT05746; Document No.: M-362603-01-2; February 15, 2010; Pages: 76	870.1300	48024604
5	Gmelin, C.; BYF 14182 + clothianidin FS 66.5+207 g/L - Acute eye irritation on rabbits; Bayer Schering Pharma AG, Wuppertal, Germany; Report No.: AT05732; Document No.: M-362457-01-2; February 15, 2010; Pages: 24	870.2400	48024605
6	Gmelin, C.; BYF 14182 + clothianidin FS 66.5+207 g/L - Acute skin irritation/corrosion on rabbits; Bayer Schering Pharma AG, Wuppertal, Germany; Report No.: M-362461-01-2; Document No.: M-362461-01-2; February 15, 2010; Pages: 25	870.2500	48024606
7	Blanck, M.; BYF 14182 + clothianidin FS 66.5+207 g/L - Evaluation of potential skin sensitization in the local lymph node assay in the mouse; Bayer CropScience, Sophia Antipolis, France; Report No.: SA 09342; Document No.: M-362273-01-2; March 04, 2010; Pages: 41	870.2600	48024607
SUPP Studies without Guideline Numbers			
8	Hines, D.; Tier 2 summary of the physical, chemical and technical properties of the plant protection product for Penclo 273.5FS; Bayer CropScience; Report No.: US0014; Document No.: M-365528-01-1; March 13, 2010; Pages: 17	SUPP	48024608
9	Rupprecht, K.; Young, B. M.; Tier 2 summary of the toxicological studies and exposure data and information on the plant protection product for Penclo 273.5FS; Bayer CropScience; Report No.: US0001; Document No.: M-365037-01-1; March 12, 2010; Pages: 25	SUPP	48024609

PRIA 2 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

3/23/09

21 Day Screen Start Date: 4-2-10

Experts In-Processing Signature: MF HARRINGTON Date 4-9-10 Fee Paid: Yes

Division management contacted on issues No Yes Date

EPA Reg. Number: <u>264-RREL</u>		EPA Receipt Date: <u>4-2-10</u>				
Items for Review				Yes	No	N/A*
1	Application Form (EPA Form 8570-1)(link to form) signed & complete including package type			X		
2	Confidential Statement of Formula all boxes completed, form signed, and dated (EPA Form 8570-4) (Link to form)			X		
	a) All inerts (link to http://www.epa.gov/opprd001/inerts/), including fragrances, approved for the proposed uses (see Footnote A) <u>see comments</u>	yes	no			
			X			
3	Certification with Respect to Citation of Data (EPA Form 8570-34) (Link to form) completed and signed (N/A if 100% repack)			X		
	Certificate and data matrix consistent			X		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	yes	no			
	If applicable, is there a letter of Authorization for exclusive use only.					
4	Formulator's Exemption Statement (EPA Form 8570-27) (Link to form) completed and signed (N/A if source is unregistered or applicant owns the technical)			X		
	Data Matrix (EPA Form 8570-35) (Link to form) both internal and external copies (PR 98-5) (Link to PR 98-5) completed and signed (N/A if 100% repack)			X		
5	a) Selective Method (Fee category experts use)	yes	no			
		X				
	b) Cite-All (Fee category experts use)					
	c) Applicant owns all data (Fee category experts use)					
6	5 Copies of Label (link to http://www.epa.gov/oppfead1/labeling/lrm/) (Electronic labels on CD are encouraged and guidance is available)(link to http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm#labels)			X		

inerts need to
be added to oppmt -
See inert team
Alba or Kerry.
Thanks -
✓

7	Is the data package consistent with PR Notice 86-5 (link to PRN 86-5)	X		
8	Notice of Filing (link to http://www.epa.gov/pesticides/regulating/tolerance_petitions.htm) included with petitions (link to http://www.epa.gov/pesticides/regulating/tolerances.htm)			X
9	If applicable for conventional applications, reduced risk rationale (link to http://www.epa.gov/opprd001/workplan/reducedrisk.html)			X
10	Required Data (link to http://www.epa.gov/pesticides/regulating/data_requirements.htm) and/or data waivers. See Footnote C.			
	a) List study (or studies) not included with application			

Comments:

Studies pass 80-5 review MRID 480246
E-submission

Inerts [REDACTED]
are NOT in the system. Contacted registrants regarding
inerts on 4/15/10. Told registrants, ^{the} agency needs 100%
composition (CAS#, chemical names, % w/w components)
according to inert team on 7th floor. Directed
registrant to send any further questions/comments
to PM (Venus Eagle)

MP 4/16/10

MRID 480246

* N/A – Not Applicable

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses. If an unapproved inert is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses **even if a product is currently registered** by consulting the inert Web

site [link to <http://www.epa.gov/opprd001/inerts/lists.html>] and if the inert is not approved, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient**. Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at inertsbranch@epa.gov and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the Chief of Microbial Pesticides Branch [Link to http://www.epa.gov/oppbppd1/biopesticides/contacts_bppd.htm].

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information [link to <http://www.epa.gov/opprd001/inerts/tips.pdf>] must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

Unapproved Inerts Identified on CSFs

All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R311, R312 or R313), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)
3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.

Script for Rejection Phone calls

Contact Name: Tamin Huang
Phone #: 919-549-2634
Email: tamin.huang@bayercropscience

out of the country. Been in contact
with Mel Tolliver (mel.tolliver@bayercropscience.com)
+ Dirk Friedrichsdorf (dirk.friedrichsdorf@bayercropscience.com)

First Call/Initials: mf

Date: 4/15/10

Time: 2:30 pm

Second Call/Initials:

Date: 4/16/10

Time:

This is _____, EPA contractor.

I'm calling regarding your submission in support of

Pencils 273 EFs

We have found the following deficiencies regarding:

PR Notice 86.5: Yes or No

Volume/Study Title:

Volume/Study Title:

Volume/Study Title:

Additional volumes continued on back of page: Yes or No

Application Package: Yes or No

Inerts do
NOT pass

Inerts

not in the system. Need 100%

composition of both inerts

Found additional info in studies but still
not 100% composition.

These deficiencies have been approved by EPA.

The corrections can be faxed to 703-305-5060/Attn: _____.

Second Call/Email:

If we do not receive the corrections by _____, we will process
your submission, accordingly. Please direct all future calls and
correspondence to the appropriate EPA Risk Manager.

Inert ingredient information may be entitled to confidential treatment

FEE FOR SERVICE



United States
Environmental Protection Agency
Washington, DC 20460

☒ Registration
☐ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 264-XXXX RREL	2. EPA Product Manager Venus Eagle	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) PENCLO 273.5FS	PM# 01	
5. Name and Address of Applicant (Include ZIP Code) Bayer Cropscience 2 T.W. Alexander Drive Research Triangle Park, NC 27709 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input checked="" type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

REG FEE: PRIA R010 with a PRIA fee of \$ 542,115

JUSTIFICATIONS: As part of the PRIA R010 Registration application of a new fungicide, Penflufen (New Active Ingredient, Food Use, \$ 542,115) Please see the enclosed cover letter for details.

CONTACT: Jamin Huang e-mail address: jamin.huang@bayercropscience.com

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input checked="" type="checkbox"/> Metal	
* Certification must be submitted				<input type="checkbox"/> Plastic	
If "Yes" Unit Packaging wgt. No. per container		If "Yes" Package wgt. No. per container		<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input type="checkbox"/> Other (Specify) _____	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 2.5, 15, 30, 50, 260 gallons		5. Location of Label Directions <input checked="" type="checkbox"/> ON CONTAINER	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name Jamin Huang, Ph.D.		Title Senior Regulatory Manager		Telephone No. (Include Area Code) 919-549-2634	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					6. Date Application Received (Stamped)
2. Signature 		3. Title Senior Regulatory Manager		 M-365409-01-1	
4. Typed Name Jamin Huang, Ph.D.		5. Date March 31, 2010			



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reviewing the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, Collection Strategies Division (2822T), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington, DC 20460. Do not send the completed form to this address.

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number Bayer CropScience, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709 (919-549-2634)	EPA Registration Number/File Symbol 264-XXXX
Active Ingredient(s) and/or representative test compound(s) Penflufen, Clothianidin	Date March 31, 2010
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Seed Treatment, Terrestrial Food Use	Product Name PENCLO 273.5FS

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

<input type="checkbox"/> I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).	<input checked="" type="checkbox"/> I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).
--	---

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☐ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel, or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature

Date

03/31/2010

Typed or Printed Name and Title

Jamin Huang, Senior Regulatory Manager



Bayer CropScience



March 31, 2010

ATTENTION:

Ms. Venus Eagle (PM 01, RD, Insecticide-Rodenticide Branch)
Document Processing Desk (REGFEE)
Office of Pesticide Programs (7505P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, Virginia 22202-4501
U.S.A.

Ms. Karen Reynolds
Director, Submission and Information Management Division
Pest Management Regulatory Agency
2720 Riverside Drive
Ottawa, Ontario K1A 0K9
Canada

Ms. Pat Robinson
Senior Evaluator, Pesticides Program
Australian Pesticides and Veterinary Medicines Authority
18 Wormald Street
Symonston, ACT, 2609
Australia

Re: Submission of Applications for Registration of New Active Ingredient, Penflufen

Dear Ms. Eagle, Ms. Reynolds and Ms. Robinson,

Bayer CropScience (BCS) is herein submitting applications for registration of Penflufen, a new fungicidal active ingredient that has not been previously registered in the U.S, Canada or Australia. Penflufen is being submitted jointly to US-EPA, Canada-PMRA and Australia-APVMA for a US-Canada-Australia joint review. This cover letter provides general information about this joint review. Specific country administrative requirements are in Appendix 1 (for the U.S.), Appendix 2 (for Canada) and Appendix 3 (for Australia). This complete cover letter is to be sent to all of the three national authorities to ensure transparency and open communication.

Included in this submission is a dossier with the necessary data to support the proposed registration of Penflufen TC (technical active ingredient) for the U.S., Canada and Australia,



M-365801-01-1

E-SUBMISSION

and its associated uses for the U.S. and Canada. The dossier also includes a petition for establishment of tolerances/Maximum Residue Limits (MRLs) for the proposed seed treatment uses for penflufen on terrestrial food crops alfalfa, Tuberous and corm vegetables CSG (Crop Subgroup) 1C, Soybeans, Legume vegetables CG (Crop Group) 6, Foliage of Legume vegetables CG 7, Cereal grains CG 15, Forage, fodder and straw of Cereal grains CG 16, and Oilseeds CG 20 including cotton, gin byproducts, and also for the use on potato *via* in-furrow application. As will be discussed later, a partial data set is provided at this time to support the proposed seed treatment uses in cereals in Australia. Biological data will be submitted to the APVMA in October 2010, as a time-shift submission.

Product Benefits

Penflufen, also designated as BYF 14182 (the research identification number), is a novel fungicide with a broad spectrum of activity against numerous fungal diseases, including *Rhizoctonia* in a range of crops, leaf stripe (barley), and smuts and bunts (barley, wheat). The biochemical mode of action of penflufen involves the inhibition of the enzyme succinate dehydrogenase (Complex II) within the fungal mitochondrial respiratory chain, thus blocking electron transport. Penflufen will provide users with an outstanding level of disease control and an important tool for resistance management. In the US and Canada, total seasonal application rates for the proposed seed treatment uses range between 1 and 10 g ai/ha, the only exception being potato. For potato, the proposed rates *via* seed-piece treatment is no more than 80 g ai/ha, with a total rate for combination of in-furrow application and seed-piece treatment being no more than 160 g ai/ha. In Australia, the maximum application rate for the proposed seed treatment use on wheat and barley is 20 g ai/ha. More detailed information on the benefits/value of penflufen is included with dossiers supporting the applications for registration of the end-use products.

International Joint Review

As discussed above, penflufen is being submitted concurrently to US-EPA, Canada-PMRA and Australia-APVMA, who have agreed upon a joint review with the intent of creating a mutually-approved list of endpoints. The primary focus of the Joint Review will be Penflufen TC under its most intensive and complete use patterns (critical GAP) which are covered by the PEN 240FS and PENRED 240FS formulations. In addition to these two end-use products, containing penflufen as the sole active ingredient, five additional end-use products, containing two or more active ingredients, are being submitted to US-EPA and Canada-PMRA. BCS are requesting that US-EPA and Canada-PMRA work jointly to harmonize the review of all seven formulations. The same Joint Review Dossier covering Penflufen TC, with additional PEN 240FS and PENRED 240FS data and GAP information will be submitted to US-EPA, Canada-PMRA and Australia-APVMA. BCS Australia is not currently in a position to submit a final package for the approval of an end use product. Biological data (residue and crop safety/efficacy data) supporting PENRED 240FS use in Australia will be submitted to the APVMA in October, 2010, as a time-shift submission. While, there may be minor impacts on the GAP at that time, any changes will be clearly explained.

The key objectives of the Joint Review are to come to a uniform residue definition, to harmonize MRLs and to establish reciprocal import tolerances in order to avoid trade barriers among the U.S., Canada, and Australia. Ordinarily, a tolerance would be required if the pesticide is used in a manner which has a reasonable likelihood to produce residues in food. Residue field trials at the proposed seed treatment rates and exaggerated rates and total radioactive residue studies (TRR) have demonstrated that there is no reasonable expectation of finite measurable residues in crops grown from penflufen-treated seed or from potato in-furrow use. In the United States, these crops would normally be classified as a food use without a tolerance under the threshold of regulation guidance. Nevertheless, in order to promote international MRL harmonization and avoid any potential trade irritants, BCS proposes each of the joint review partners establish penflufen tolerances for all commodities at 0.01 ppm (LOQ), which corresponds with the European default MRLs of 0.01 ppm.

For Europe, the dossier for Penflufen TC, and its proposed use on potato based on a European-specific Penflufen FS050 formulation, was submitted the United Kingdom's Chemicals Regulation Directorate (as the Rapporteur Member State on behalf of the EU Commission) on December 4, 2009. This dossier passed the check of completeness on February 16, 2010. BCS supports sharing of the Draft Assessment Report (DAR) and/or UK-CRD study reviews with US-EPA, Canada-PMRA and Australia-APVMA.

Additionally, BCS Brazil plans to submit its country dossier of Penflufen TC and its proposed use on cotton, dry beans, soybeans, corn, rice and potato to the Brazilian Authorities around August, 2010. Even though Brazil is not part of the joint review, BCS supports the Brazilian Authorities being an observer to the US-Canada-Australia joint review.

Pursuant to the agreed-upon joint review, BCS hereby authorizes all involved authorities to communicate and share data reviews for penflufen technical and associated end-use products among the Joint Review partners (EPA, PMRA and APVMA), and also with UK (CRD) if there is an interest from CRD.

End-Use Products

In addition to the application for Penflufen TC (technical active ingredient), applications are submitted to EPA and PMRA for registration of seven end-use products containing penflufen, five of which contain other active ingredients. As mentioned earlier, for Australia, an application for registration of only PENRED 240FS is submitted at this time. The active ingredients and their gram/liter information for the proposed end-use products are provided in the table below.

Product name	active ingredient(s)	g/L
PEN 240FS	penflufen	241 (neutral)
PENRED 240FS	penflufen	240 (red)
PENPRO 118FS	penflufen	100
	prothioconazole	18
PENTRI 308FS	penflufen	154
	trifloxystrobin	154
PENCLO 273.5FS	penflufen	66.6
	clothianidin	206.5
PENPROME 176.6FS	penflufen	38.4
	prothioconazole	76.8
	metalaxyl	61.4
PENCLOTRIME 310.68FS	penflufen	10.7
	clothianidin	290.0
	trifloxystrobin	7.15
	metalaxyl	7.15

Certain of the end-use products proposed for registration in the U.S. and Canada represent new crop uses for the co-formulated active ingredients (prothioconazole, trifloxystrobin and/or clothianidin). Therefore, in conjunction with the applications to register these penflufen products, BCS is submitting data to support the new uses for the co-formulated actives. These new uses for clothianidin, prothioconazole and trifloxystrobin are supported by a common data set in the U.S. and Canada. Details on the registration statuses of these proposed new uses were previously communicated to both EPA and PMRA in discussions on the joint review project. BCS would encourage EPA and PMRA to work cooperatively on the review of these new crops uses for clothianidin, prothioconazole and trifloxystrobin, and to work towards the establishment of harmonized tolerances/MRLs. The regulatory actions and petitions required to supporting these new uses for the co-formulated active ingredients in the U.S. and Canada are presented in Appendix 1 and 2, respectively.

Several different product names were used for the same end-use product in different study reports. Appendix 4 provides a list of different product names used for each of the same end-use products in different study reports that are included in this dossier.

Electronic Dossier

The Joint Review dossier supporting registration of Penflufen TC and associated uses is an update to the Annex II dossier that has been submitted in support of the registration of penflufen in Europe. Prior to this Joint Review submission, BCS submitted the Annex II for Penflufen TC (and the Annex III for European-specific end-use product Penflufen FS050) to UK CRD on December 4, 2009. After the Check of Completeness by UK CRD as European Rapporteur Member State on February 16, 2010, an updated version of the dossier was submitted to the European Commission, European Food Safety Authority (EFSA) and all European Member States in the middle of March, 2010. These updates are included in the US-Canada-Australia Joint Review electronic Dossier.

A. Study Data

BCS incorporates all the study data from the Annex II (active ingredient) of the European Dossier into the US-Canada-Australia Joint Review Dossier. Because of differences in use profiles, data requirements and end-use products, the Annex II dossier submitted to UK CRD contains certain studies that would not typically be required by the U.S., Canada or Australia. However, to facilitate communication amongst all review partners, those European-specific studies contained in the Annex II dossier for Europe have been included, for information purpose only, in the Joint Review dossier.

Also, in comparison to the European dossier submitted to UK CRD, the BCS Reference Number for reports included in the Joint Review dossier has been adjusted to accommodate the US EPA 86-5 format requirement. The BCS number is built to support the document lifecycle. As an example of **M-004711-01-1**, “**M-004711**” reflects the basic document number to include all versions and editions. “**-01**” reflects the version of the document. “**-1**” reflects the format of the document. If a study is performed within the EU, its EU version will receive the first Edition number “-1”. If this study is reformatted per the US EPA 86-5 guideline for submission in the US, it will receive the Edition number “-2”. For the studies that are performed in the US and directly formatted according to the US EPA 86-5 guideline, all will be assigned “-1”.

All of the three Joint Review partners are receiving the same documents that are reformatted according to the US EPA 86-5 guideline. UK CRD has not received the reformatted documents. To facilitate a smooth communication with CRD, BCS encourages all of the national authorities involved to use only the BCS Document Number excluding the format information, i.e. M-004711-01 instead of M-004711-01-1.

B. Tier II Summaries and Tier III Summaries

The Tier II Summaries in both Annex II and Annex III of the Joint Review Dossier only cover the proposed uses and formulations to be registered within the countries of the Joint Review partners. Those studies that have been replaced or are not required (e.g., specific to Europe only) are not cited within the Tier II summary of the Joint Review dossier. However, the study reports are included in the dossier as Documents. Refer to Appendix 5 for a list of those study reports that are included in the Joint Review dossier, but not in the Tier II summary.

The Tier II summaries in the Joint Review Dossier have been updated with the references to the 86-5 formatted documents.

The Tier III List of Endpoints document has been updated to include endpoints from both the EU and Joint Review submissions. The Tier III Overall summary for the EU covered the active ingredient and the use pattern associated with the formulation Penflufen FS050. For the Joint Review, it has been updated to cover use patterns associated with the formulations PEN 240FS and PENRED 240FS. In addition, Document N of the Joint Review includes detailed documents supporting the Tier III summary covering drinking water exposure, aquatic exposure, dietary (food and water) exposure and occupational exposure for both the U.S. and Canada plus consolidated assessment summaries of ecological and human risk. BCS has included the Tier II, Tier III and Document N risks assessments as both Word and PDF files to assist reviewers if they wish to cut and paste any of the information for use in their assessment documents. Penflufen use rates in PEN 240FS and PENRED 240FS are equivalent to or higher than the proposed use rate in mixture formulations with clothianidin, prothioconazole, trifloxystrobin, and metalaxyl namely PENCLO 273.5FS, PENPRO 118FS, PENTRI 308FS, PENPROME 177FS, and PENCLOTRIME 310.68FS. The risk assessments in Document N for PEN 240FS and PENRED 240FS uses are therefore applicable to the penflufen component of the mixtures.

C. US EPA MRID Numbers:

For the dossiers submitted to the U.S., the MRID numbers are assigned shortly before submission. These are assigned in sequence with the OPPTS number. Because the initial creation of the dossier in OECD number order and a very late conversion of the OECD structure into an OPPTS structure, BCS is not able to provide the MRID numbers within the Tier II summaries. To make cross-reference easier during the joint review, BCS will provide a list of all submitted documents with the BCS reference number, the MRID number, the OECD number and the OPPTS number.

D. Dossier formats:

Australia:

The OECD Annex II dossier for Penflufen TC and the OECD Annex III dossiers for the end-use products PEN 240FS and PENRED 240FS are submitted in paper as required for archive purposes. A data-list is submitted in the APVMA required xml format. In addition to this, a complete electronic version of the OECD structured dossier is provided in a XML/PDF format which can be viewed using a standard Web Browser like the Internet Explorer. The Tier II Summaries contain hyperlinks to the cited studies to ease the review process. Further details regarding the dossiers supporting the requested actions for Australia are outlined in Appendix 3.

Canada:

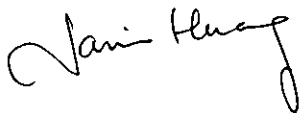
For Canada, the dossiers are submitted in the PMRA required eIndex format. The dossier for Penflufen TC follows the OECD Annex II structure with the study data assigned using the original OECD guideline numbers. The dossiers for the 7 end-use products follow the OECD Annex III structure and numbering system. For each dossier, the hyperlinks within the Tier II summaries are deactivated because the PMRA eIndex system is not able to redirect the hyperlinks within their in-house system after the import. Further details regarding the dossiers supporting the requested actions for Canada are outlined in Appendix 2.

USA:

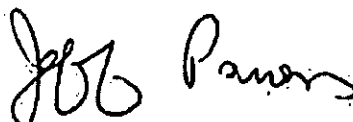
Due to limitations of the EPA ePrism format, the dossiers are not submitted with the OECD numbers. All documents of the OECD Dossier are assigned according to OPPTS number. Each document (study report, summary, etc.) in the dossier has an assigned MRID number. The hyperlinks within the Tier II summaries are deactivated because the EPA ePrism system is not capable to redirect the hyperlinks within their in-house system after the import. Further details regarding the dossiers supporting the requested actions for the US are outlined in Appendix 1.

If you have any questions regarding this submission, please let us know.

Sincerely,



Jamin Huang, Ph.D.
Senior Regulatory Manager
BCS-USA
Jamin.huang@bayercropscience.com



Jeff Parsons
Senior Regulatory Manager
BCS-Canada
jeff.parsons@bayercropscience.com



Narelle Cooke
Regulatory Affairs Associate
BCS-Australia
narelle.cooke@bayercropscience.com

Attachments

cc: Lois Rossi, EPA, OPP, RD (via e-mail)
Meredith Laws, EPA, OPP, RD (via e-mail)
Teresa Downs, EPA, OPP, RD (via e-mail)
Marion Law, PMRA (via e-mail)
Martin Vaupel, BCS-Monheim (Germany), Reg-Affairs
Marcia Paranhos, BCS-Brazil, Reg-Affairs
Dirk Fredrichsdorf, BCS-USA, Reg-Affairs, Documentation

Appendix 1 (for the U.S.)

Specific to the Administrative Requirements in the U.S.

1. PRIA Actions:

As previously discussed and agreed with the Agency, the following five PRIA actions are required to support the registrations of Penflufen TC and its 7 end-use products (PEN 240FS, PENRED 240FS, PENPRO 118FS, PENTRI 308FS, PENCLO 273.5FS, PENPROME 177FS and PENCLOTRIME 310.68FS). To support some of the proposed end-use products, this submission also includes all the necessary data required for the registration of new uses from other active ingredients, such as, clothianidin, trifloxystrobin and prothioconazole. We request an extension of the decision time for the PRIA R273 (2), R170 and R274 actions below to be synchronized with the PRIA 010 action for the Penflufen registration application.

PRIA actions	EPA PRIA #	PRIA fee
Penflufen. New food use to include all of the proposed seed treatment (ST) uses and potato in-furrow use, and 7 proposed end-use products containing penflufen	R010	\$ 542,115
To establish clothianidin tolerance for Oilseed CSG 20A and to register its ST use on Oilseed CSG 20A	R273	\$ 43,575
To establish trifloxystrobin tolerance for alfalfa (based on TRR) and to register its ST use on alfalfa	R273	\$ 43,575
To establish prothioconazole tolerance for rice and to register its foliar use on rice	R170	\$ 57,120
To establish prothioconazole tolerances (based on TRR) and to use prothioconazole tolerances established for foliar/soil application for the proposed ST uses	R274	\$ 261,450

Registration actions required for clothianidin in the US:

We are enclosing a tolerance petition for clothianidin to support the expansion of the established tolerance for canola (0.01 ppm) to the Rapeseed Subgroup 20A based on the canola residue data that have been reviewed and accepted by the US EPA (MRID # 45416311, 45422615, 45422616 and 45422617). This petition is necessary in order to include mustard

(oilseed and condiment), along with canola and rapeseed (approved), in the proposed use of PENCLOTRIME 310.68FS. A similar petition for clothianidin MRL in/on Rapeseed Subgroup 20A based on the same canola residue data is currently pending at the Canadian PMRA. For PENCLOTRIME 310.68FS, the needed tolerances and seed treatment uses for trifloxystrobin (Trifloxystrobin Flowable Fungicide, EPA Reg. No. 264-989) and metalaxyl (Allegiance-FL Seed Treatment Fungicide, EPA Reg. No. 264-935) on these crops have been approved by the Agency.

Registration actions required for trifloxystrobin in the US:

We are enclosing a petition based on a limited uptake/total radioactive residue (TRR) study to establish a tolerance on alfalfa. This petition is necessary to allow use of PENTRI 308FS on alfalfa. Tolerances and seed treatment uses for all other crops on the labels for the products PENCLOTRIME 310.68FS and PENTRI 308FS have been approved by the Agency (Trifloxystrobin Flowable Fungicide, EPA Reg. No. 264-989).

Registration actions required for prothioconazole in the US:

We are enclosing two petitions to support registration of the products PENPROME 177FS and PENPRO 118FS. One petition is to establish tolerances on rice based on data from foliar residue trials. The second petition is to establish tolerances on potato and alfalfa based on a limited uptake/total radioactive residue (TRR) studies and to allow tolerances based on approved foliar uses to support proposed seed treatment use on rice, soybeans and Crop Subgroup 6C. Tolerances and seed treatment uses on barley, triticale and wheat have been approved by the Agency (Proceed MD Fungicide, EPA Reg. No. 264-1072).

2. Pesticide Petitions and Notices of Filing

Enclosed are also four sets of Pesticide Petitions (for penflufen, clothianidin, trifloxystrobin, and prothioconazole) containing the following:

Section A: The name, chemical identity and composition of the pesticide active ingredient and its pesticide product(s).

Section B: The amount, frequency and time of application of the pesticide product.

Section C: A summary of the toxicology database for active ingredient and its end-use products.

Section D: Residue chemistry data and analytical methodology used in support of the proposed tolerances for active ingredient.

Section E: Practical methods for removing residues in excess of the proposed tolerance.

Section F: The proposed tolerances for residues of active ingredient in or on a number of commodities.

Section G: Reasonable grounds in support of this petition. This section summarizes the proposed tolerances for active ingredient for the crop use and the supporting data.

Also included with this submission are four Notices of Filing summary document consistent with section 408(d) of FFDCA, as amended by the Food Quality Protection Act. These are for penflufen, clothianidin, trifloxystrobin, and prothioconazole. BCS also authorizes for these four summaries to be published in the Federal Register in a notice of receipt of the petition. While these four summaries represent BCS' evaluation of the chemicals, we understand that EPA has not evaluated the sufficiency of the submitted data or whether the data fully support these four petitions.

3. Organization of Documents within the E-Prism dossier

Dossier 1 – Petition for tolerances and Notice of Filing for Penflufen

(This petition supports the actions requested in Dossiers 2 to Dossier 9)

Cover letter for Penflufen joint review

Copy of PRIA check for Penflufen \$542,115 (PRIA R010)

Petition for Tolerance

Notice of Filing

Dossier 2 – Penflufen TC – New Chemical (Technical Active Ingredient)

Cover letter for Penflufen TC

Cover letter for Penflufen joint review

EPA Form 8570-1 dated March 31, 2010

A copy of PRIA check for Penflufen \$ 542,115 (PRIA R010)

EPA Form 8570-34 dated March 31, 2010

Data Matrix for Penflufen TC dated March 31, 2010 (Agency copy)

Data Matrix for Penflufen TC dated March 31, 2010 (Public copy)

Proposed labeling for Penflufen TC dated March 31, 2010

Confidential Statement of Formula for Penflufen TC

Transmittal documents listing enclosed study reports

Dossier 3 – PEN 240FS – New Formulation

Cover letter for PEN 240FS
Cover letter for Penflufen joint review
EPA Form 8570-1 dated March 31, 2010
A copy of PRIA check for Penflufen \$ 542,115 (PRIA R010)
EPA Form 8570-34 dated March 31, 2010
Data Matrix for PEN 240FS dated March 31, 2010 (Agency copy)
Data Matrix for PEN 240FS dated March 31, 2010 (Public copy)
Proposed labeling for PEN 240FS dated March 31, 2010
Confidential Statements of Formula for PEN 240FS
Transmittal documents listing enclosed study reports

Dossier 4 – PENRED 240FS – New Formulation

Cover letter for PENRED 240FS
Cover letter for Penflufen joint review
EPA Form 8570-1 dated March 31, 2010
A copy of PRIA check for Penflufen \$ 542,115 (PRIA R010)
EPA Form 8570-34 dated March 31, 2010
Data Matrix for PENRED 240FS dated March 31, 2010 (Agency copy)
Data Matrix for PENRED 240FS dated March 31, 2010 (Public copy)
Proposed labeling for PENRED 240FS dated March 31, 2010
Confidential Statements of Formula for PENRED 240FS
Transmittal documents listing enclosed study reports

Dossier 5 – PENCLOTRIME 310.68FS – New Formulation

Cover letter for PENCLOTRIME 310.68FS
Cover letter for Penflufen joint review
EPA Form 8570-1 dated March 31, 2010
A copy of PRIA check for Penflufen \$ 542,115 (PRIA R010)
EPA Form 8570-27 dated March 31, 2010
EPA Form 8570-34 dated March 31, 2010
Data Matrix for PENCLOTRIME 310.68FS dated March 31, 2010 (Agency copy)
Data Matrix for PENCLOTRIME 310.68FS dated March 31, 2010 (Public copy)
Proposed labeling for PENCLOTRIME 310.68FS dated March 31, 2010
Confidential Statements of Formula for PENCLOTRIME 310.68FS
Transmittal documents listing enclosed study reports

Dossier 6 – PENPROME 177FS – New Formulation

Cover letter for PENPROME 177FS
Cover letter for Penflufen joint review
EPA Form 8570-1 dated March 31, 2010
A copy of PRIA check for Penflufen \$ 542,115 (PRIA R010)

EPA Form 8570-27 dated March 31, 2010
EPA Form 8570-34 dated March 31, 2010
Data Matrix for PENCLOME 177FS dated March 31, 2010 (Agency copy)
Data Matrix for PENCLOME 177FS dated March 31, 2010 (Public copy)
Proposed labeling for PENCLOME 177FS dated March 31, 2010
Confidential Statements of Formula for PENCLOME 177FS
Transmittal documents listing enclosed study reports

Dossier 7 – PENPRO 118FS – New Formulation

Cover letter for PENPRO 118FS
Cover letter for Penflufen joint review
EPA Form 8570-1 dated March 31, 2010
A copy of PRIA check for Penflufen \$ 542,115 (PRIA R010)
EPA Form 8570-34 dated March 31, 2010
Data Matrix for PENPRO 118FS dated March 31, 2010 (Agency copy)
Data Matrix for PENPRO 118FS dated March 31, 2010 (Public copy)
Proposed labeling for PENPRO 118FS dated March 31, 2010
Confidential Statements of Formula for PENPRO 118FS
Transmittal documents listing enclosed study reports

Dossier 8 – PENTRI 308FS – New Formulation

Cover letter for PENTRI 308FS
Cover letter for Penflufen joint review
EPA Form 8570-1 dated March 31, 2010
A copy of PRIA check for Penflufen \$ 542,115 (PRIA R010)
EPA Form 8570-34 dated March 31, 2010
Data Matrix for PENTRI 308FS dated March 31, 2010 (Agency copy)
Data Matrix for PENTRI 308FS dated March 31, 2010 (Public copy)
Proposed labeling for PENTRI 308FS dated March 31, 2010
Confidential Statements of Formula for PENTRI 308FS
Transmittal documents listing enclosed study reports

Dossier 9 – PENCLO 273.5FS – New Formulation

Cover letter for PENCLO 273.5FS
Cover letter for Penflufen joint review
EPA Form 8570-1 dated March 31, 2010
A copy of PRIA check for Penflufen \$ 542,115 (PRIA R010)
EPA Form 8570-27 dated March 31, 2010
EPA Form 8570-34 dated March 31, 2010
Data Matrix for PENCLO 273.5FS dated March 31, 2010 (Agency copy)
Data Matrix for PENCLO 273.5FS dated March 31, 2010 (Public copy)
Proposed labeling for PENCLO 273.5FS dated March 31, 2010
Confidential Statements of Formula for PENCLO 273.5FS

Transmittal documents listing enclosed study reports

Dossier 10 – Petition for tolerances and Notice of Filing for Clothianidin

(This petition supports the actions requested in Dossiers 11 and 12)

Cover letter for Penflufen joint review

Copy of PRIA check for Clothianidin Technical \$43,575 (PRIA R273)

Petition for Tolerance

Notice of Filing

Dossier 11 – Clothianidin Technical: New Use Oilseed Mustard

Cover letter for Clothianidin Technical

Cover letter for Penflufen joint review

EPA Form 8570-1 dated March 15, 2010

A copy of PRIA check for Clothianidin Technical \$ 43,575 (PRIA R273)

EPA Form 8570-34 dated March 15, 2010

Data Matrix for Clothianidin Technical dated March 15, 2010 (Agency copy)

Data Matrix for Clothianidin Technical dated March 15, 2010 (Public copy)

Proposed labeling for Clothianidin Technical dated March 15, 2010

Dossier 12 – Prosper T400 (EPA Reg. No. 264-1034)

Cover letter for Prosper T400

Cover letter for Penflufen joint review

EPA Form 8570-1 dated March 31, 2010

A copy of PRIA check for Clothianidin Technical \$ 43,575 (PRIA R273)

EPA Form 8570-27 dated March 31, 2010

EPA Form 8570-34 dated March 31, 2010

Data Matrix for Prosper T400 dated March 31, 2010 (Agency copy)

Data Matrix for Prosper T400 dated March 31, 2010 (Public copy)

Amended labeling for Prosper T400 dated March 31, 2010

Amended labeling with all of the revision highlighted in yellow, in relation to the approved labeling dated September 11, 2009.

Dossier 13 – Petition for tolerances and Notice of Filing for Trifloxystrobin

(This petition supports the actions requested in Dossiers 14 and 15)

Cover letter for Penflufen joint review

Copy of PRIA check for Trifloxystrobin Technical \$43,575 (PRIA R273)

Petition for Tolerance

Notice of Filing

Dossier 14 – Trifloxystrobin Technical (264-776): New ST Use on Alfalfa

Cover letter for Trifloxystrobin

Cover letter for Penflufen joint review

Application form 8570-1 for Trifloxystrobin Technical
Data citation form 8570-34 for Trifloxystrobin Technical
Data Matrix for Trifloxystrobin Technical
Copy of PRIA check for Trifloxystrobin Technical \$43,575 (PRIA R273)
Transmittal documents listing enclosed study reports for Trifloxystrobin Technical
Proposed label for Trifloxystrobin Technical

Dossier 15 – Trifloxystrobin Flowable (264-989): New ST Use on Alfalfa

Cover letter for Trifloxystrobin Flowable
Cover letter for Penflufen joint review
Application form 8570-1 for Trifloxystrobin Flowable Fungicide
Data citation form 8570-34 for Trifloxystrobin Flowable Fungicide
Data Matrix for Trifloxystrobin Flowable Fungicide
Copy of PRIA check for trifloxystrobin petition \$43,575 (PRIA R273)
Proposed label for Trifloxystrobin Flowable Fungicide

Dossier 16 – Petition for tolerances and Notice of Filing for Prothioconazole Foliar Use on Rice

(This petition supports the actions requested in Dossiers 17 and 18)
Copy of PRIA check for Prothioconazole Technical \$ 57,120 (PRIA R170)
Petition for Tolerance
Notice of Filing

Dossier 17 – Prothioconazole Technical (264-824): New Foliar Use on Rice

Cover letter for Prothioconazole
Cover letter for Penflufen joint review
Application form 8570-1 for Prothioconazole Technical
Data citation form 8570-34 for Prothioconazole Technical
Data Matrix for Prothioconazole Technical
Copy of PRIA check for Prothioconazole Technical \$ 57,120 (PRIA R170)
Transmittal documents listing enclosed study reports for Prothioconazole Technical
Proposed label for Prothioconazole Technical

Dossier 18 – Proline 480 SC Fungicide (264-825): New Foliar Use on Rice

Cover letter for Proline 480 SC
Cover letter for Penflufen joint review
Application form 8570-1 for Proline 480 SC Fungicide
Data citation form 8570-34 for Proline 480 SC Fungicide
Data Matrix for Proline 480 SC Fungicide
Copy of PRIA check for prothioconazole petition \$ 57,120 (PRIA R170)
Proposed label for Proline 480 SC Fungicide

Dossier 19 – Petition for tolerances and Notice of Filing for Prothioconazole Seed Treatment

(This petition supports the actions requested in Dossiers 20 and 21)

Cover letter for Penflufen joint review

Copy of PRIA check for Prothioconazole Technical \$ 261,450 (**PRIA R274**)

Petition for Tolerance

Notice of Filing

Dossier 20 – Prothioconazole Technical (264-824): New Seed Treatment Uses

Cover letter for Prothioconazole

Cover letter for Penflufen joint review

Application form 8570-1 for Prothioconazole Technical

Data citation form 8570-34 for Prothioconazole Technical

Data Matrix for Prothioconazole Technical

Copy of PRIA check for prothioconazole petition \$ 261,450 (PRIA R274)

Transmittal documents listing enclosed study reports for Prothioconazole Technical

Proposed label for Prothioconazole Technical

Dossier 21 – Proline 480 SC Fungicide (264-825): Seed Treatment Uses

Cover letter for Proline 480 SC

Cover letter for Penflufen joint review

Application form 8570-1 for Proline 480 SC Fungicide

Data citation form 8570-34 for Proline 480 SC Fungicide

Data Matrix for Proline 480 SC Fungicide

Copy of PRIA check for prothioconazole petition \$ 261,450 (PRIA 274)

Proposed label for Proline 480 SC Fungicide

Appendix 2 (for Canada)

Specific to the Administrative Requirements in Canada

The following dossiers are submitted to the PMRA in support of the requested registration actions for Penflufen TC, the seven penflufen-containing end-use products, and the associated co-formulated active ingredients (prothioconazole and trifloxystrobin). Accompanying each dossier are supporting data, summaries and the required administrative documents (cover letter; proposed label; Application for New or Amended Registration Form; Statement of Product Specification Form; Fee Form; application fee).

Dossier 1, Application for Registration of Penflufen TC (technical active ingredient):

This dossier includes all supporting documentation for registration of Penflufen TC (technical active ingredient) and the associated uses, as well as the establishment of MRLs for all proposed crops use for penflufen. The dossier is based on the OECD Annex II structure, and as such includes residues studies, soil dissipation studies, and risk assessment for penflufen which would normally be included with the applications for registration of the end-use products under the PMRA DACO numbering system.

Dossier 2, Application for registration of PEN 240FS (end-use product):

This dossier includes all supporting documentation for registration of PEN 240FS.

Dossier 3, Application for registration of PENRED 240FS (end-use product):

This dossier includes all supporting documentation for registration of PENRED 240FS.

Dossier 4, Application for registration of PENCLOTRIME 310.68FS (end-use product):

This dossier includes all supporting documentation for registration of PENCLOTRIME 310.68FS.

Dossier 5, Application for registration of PENPROME 177FS (end-use product):

This dossier includes all supporting documentation for registration of PENPROME 177FS.

Dossier 6, Application for registration of PENPRO 118FS (end-use product):

This dossier includes all supporting documentation for registration of PENPRO 118FS. Included with this dossier are data to support the new use of prothioconazole as a seed piece treatment in potato. This use for prothioconazole is a new use for both Canada and the United States, and is supported by a common data set. As such BCS proposes that the PMRA and EPA work cooperatively on the review of these data and the establishment of harmonized MRLs for this use.

Dossier 7, Application for registration of PENTRI 308FS (end-use product):

This dossier includes all supporting documentation for registration of PENTRI 308FS. Included with this dossier are data to support the new use of trifloxystrobin as a seed treatment in alfalfa. This use for trifloxystrobin is a new use for both Canada and the United States, and is supported by a common data set. As such BCS proposes that the PMRA and EPA work cooperatively on the review of the data supporting this use for trifloxystrobin.

Dossier 8, Application for registration of PENCLO 273.5FS (end-use product):

This dossier includes all supporting documentation for registration of PENCLO 273.5FS.

Dossier 9, Application for import MRL, penflufen (Penflufen TC):

This application requests the establishment of import MRLs for penflufen in rice and cotton. Both of these crops are proposed for registration for penflufen in the United States (e.g., Pen 240FS; PENRED 240FS). BCS requests that MRLs for penflufen in rice and cotton be established to support imports of treated commodity from the United States.

Dossier 10, Application for import MRL, prothioconazole (Prothioconazole Technical Fungicide, Reg. No. 28358):

This application requests the establishment of import MRLs for prothioconazole in rice. Rice is a proposed crop use for PENPROME 177FS in the United States, and data supporting this use for prothioconazole is submitted to the EPA as one of the concurrent dossier with penflufen. BCS requests that the PMRA establish an MRL for prothioconazole in rice to support imports of treated commodity with PENPROME 177FS from the United States.

Appendix 3 (for Australia)

Specific to the Administrative Requirements in Australia

The following dossiers are submitted to the APVMA in support of the requested registration actions for Penflufen TC and the penflufen-containing end-use product, PENRED 240FS.

Dossier 1, Application for Registration of Penflufen TC (technical active ingredient) and the end-use product PENRED 240 FS:

This dossier includes all supporting documentation for registration of Penflufen TC (technical active ingredient) and partial information for registration of the end-use product PENRED 240FS. The following information is submitted to the APVMA at this time:

- Cover letter
- Combined Category 1:
 - Application for Approval of an Active Constituent
 - Application for Registration of an Agricultural Chemical Product
 - Application Overview (Part 1)
- A cheque for the amount \$48,860
- Draft product label (2 copies)
- Data list (sent to DataList@apvma.gov.au)
- OECD dossier (as detailed below)

The location within the OECD dossier of information relating to the technical active ingredient required for each APVMA “Part” is as follows:

Part 2 – Chemistry & Manufacture	OECD Annex IIA, Document KIIA, Sections 1 & 2 OECD Annex IIA, Document MIIA Sections 1 & 2
Part 3 – Toxicology	OECD Annex IIA, Document KIIA, Section 3 OECD Annex IIA, Document MIIA Section 3
Part 4 – Metabolism & Kinetics	OECD Annex IIA, Document KIIA, Sections 3 & 4 OECD Annex IIA, Document MIIA Sections 3 & 4
Part 5 – Residues & Trade	OECD Annex IIA, Document KIIA, Section 4 OECD Annex IIA, Document MIIA, Section 4
Part 6 – OH&S	OECD Annex IIA, Document N
Part 7 – Environment	OECD Annex IIA, Document KIIA, Sections 5 & 6 OECD Annex IIA, Document MIIA, Sections 5 & 6
Part 8 – Efficacy & Safety	Not relevant

Dossier 2, Application for registration of PENRED 240FS (end-use product):

This dossier includes partial supporting documentation for registration of PENRED 240FS (trade name to be advised). Biological data (residue and crop safety/efficacy data) and the relevant risk assessments supporting this formulation in Australia will be submitted to the APVMA in October 2010 under the time-shift submission. Included for review at this time are the following data parts:

Part 2 – Chemistry & Manufacture	OECD Annex IIIA, Document KIIIA, Sections 1 & 2 OECD Annex IIIA, Document MIIA Sections 1 & 2
Part 3 – Toxicology	OECD Annex IIIA, Document KIIIA, Section 3 OECD Annex IIIA, Document MIIA Section 3
Part 5 – Residues & Trade	Australian specific data to be provided in October 2010
Part 6 – OH&S	OECD Annex IIA, Document N [#]
Part 7 – Environment	OECD Annex IIA, Document KIIA, Sections 5 & 6 OECD Annex IIA, Document MIIA, Sections 5 & 6 [#]
Part 8 – Efficacy & Safety	Australian specific data to be provided in October 2010

[#].US and Canada relevant only. Australian risk assessment to be provided in October 2010.

Dossier 3, Application for registration of PEN 240FS (end-use product):

The end-use product PEN 240FS is not intended for registration in Australia. However, the PEN 240FS dossier is included for review by the APVMA as it contains supporting documentation for registration of the end-use product PENRED 240FS. The following studies are relevant to the risk assessment of the PENRED 240FS registration:

Occupational Exposure & Risk Assessment	OECD Annex IIIA, Document KIIIA, Section 3, Point 7 OECD Annex IIIA, Document MIIIA, Section 3
Ecological Effects Studies	OECD Annex IIIA, Document KIIIA, Section 6, Point 10 OECD Annex IIIA, Document MIIIA, Section 6

Appendix 4

A List of Different Product Names Used in Different Study Reports For Each of the End-Use Products

Product name	active ingredient(s)	g/L	"Equivalent names" cited in study reports/documents
PEN 240FS	penflufen	241 (neutral)	penflufen FS 240 (240 g/L)*, BYF 14182 FS 240 G
PENRED 240FS	penflufen	240 (red)	penflufen FS 240 (240 g/L)*, BYF 14182 FS 240B G, BYF 14182 FS 240 (red)
PENPRO 118FS	penflufen prothioconazole	100 18	penflufen + prothioconazole FS 118 (100+18 g/L), BYF 14182+PTZ FS 100+18A G, BYF 14182 + Prothioconazole FS 100+18 g/L, PFL+PTZ FS 118 (100+18) G, penflufen + prothioconazole FS 118 (100+18 g/L), Penflufen+Prothioconazole FS 100+18 g/l
PENTRI 308FS	penflufen trifloxystrobin	154 154	penflufen + trifloxystrobin FS 308 (154+154 g/L), TFS+BYF 14182 FS 308 (154+154) G, BYF 14182 & Trifloxystrobin FS 154 + 154 (blue), BYF 14182+Trifloxystrobin FS 154+154 g/l, BYF 14182 +TrifloxystrobinFS 308 (154+154) g/L
PENCLO 273.5FS	penflufen clothianidin	66.6 206.5	L1908, BYF 14182 + clothianidin FS 66.5+207 g/L, Clothianidin+Penflufen FS 207+66.5 g/l

PENPROME 176.6FS			L1875,
	Penflufen	38.4	metalaxyl + penflufen + prothioconazole FS 176.6 (61.4+38.4+76.8 g/L),
	Prothioconazole	76.8	Metalaxyl+Prothioconazole+BYF 14182 FS176.6 (61.4+76.8+38.4 g/L),
	metalaxyl	61.4	BYF 14182 + Prothioconazole + Metalaxyl FS 38.4+76.8+61.4
PENCLOTRIME 310.68FS			L1782,
			clothianidin + metalaxyl + penflufen + trifloxystrobin FS 315 (290+7.15+10.7+7.15 g/L)
	Penflufen	10.7	BYF 14182+CTD+MTL+TFS FS 315 G,
	clothianidin	290	BYF 14182 + Clothianidin + Metalaxyl + Trifloxystrobin FS 10,7+290+7,15+7,15,
	trifloxystrobin	7.15	Clothianidin+Metalaxyl+Penflufen+Trifloxystrobin FS 290+7.15+10.7+7.15 g/L
	metalaxyl	7.15	

*: Although the same name of “penflufen FS 240 (240 g/L)” is coincidentally used in some product chemistry reports for PEN 240FS and PENRED 240FS, these reports are placed in the correct Product Brochure for PEN 240FS or PENRED 240FS.

Appendix 5

Study reports that have been submitted to the UK-CRD with the Annex II dossier for the EU, and which are also included in the Joint Review dossier, but are not cited in the Tier II summaries of the Joint Review dossier

Document Number	OECD Data Point	Title	Author
M-358741-01-1	KIIA 1.9.3;	CSF of penflufen TC - 264-XXXX.0B0	Huang, J.
M-350548-01-2	KIIA 4.5;	Analytical method 01147 for the determination of BYF 14182 in drinking and surface water by HPLC-MS/MS	Krebber, R.; Hennes, M.
M-348690-01-2	KIIA 8.12;	Non-target terrestrial plants: an evaluation of the effects of BYF 14182 FS 50 g/L in the vegetative vigour test.	Gosch, H.
M-348694-01-2	KIIA 8.12;	Non-target terrestrial plants: an evaluation of the effects of BYF 14182 FS 50 g/L in the seedling emergence and growth test	Gosch, H.
M-344200-01-2	KIIA 8.16.1;	BYF 14182 FS 050 G: Influence on the reproduction of the collembola species Folsomia candida tested in artificial soil with 5 percent peat	Frommholz, U.
M-329498-01-2	KIIA 8.16.1;	BYF 14182 FS 050: Influence on mortality and reproduction on the soil mite species Hypoaspis aculeifer tested in artificial soil with 5 % peat	Kratz, M. A.
M-346081-01-2	KIIA 8.8.1.1;	Toxicity to the parasitoid wasp Aphidius rhopalosiphii (DESTEPHANI-PEREZ) (Hymenoptera: Braconidae) using a laboratory test BYF 14182 FS 50 G	Waibel, J.
M-349193-01-2	KIIA 8.8.1.2;	Toxicity to the predatory mite Typhlodromus pyri SCHEUTEN (Acari, Phytoseiidae) using a laboratory test; BYF 14182 FS 50 G	Waibel, J.
M-354676-01-2	KIIA 8.9.2;	BYF 14182 FS 50 G: Effects on survival, growth and reproduction on the earthworm Eisenia fetida tested in artificial soil with 5 percent peat	Leicher, T.

Bayer CropScience

**TRANSMITTAL DOCUMENT****Penflufen****EPA: New Formulation PENCLO 273.5FS****Transmittal Date**

March 31, 2010

Company Official:

Company Name:

Bayer CropScience (264)

Company Contact:

Jamin Huang

Company Telephone:

+1 919 549 2634

Bayer CropScience
Crop Protection Division
2 T.W. Alexander Drive
RTP, North Carolina 27709.



M-365812-01-1

E-SUBMISSION
16

BIBLIOGRAPHY OF SUBMITTED DATA

Study No.	Study	Guideline No.	EPA MRID No.
830 Series Product Properties Test Guidelines			
1	Hines, D.; Product chemistry of Penclo 273.SFS; Bayer CropScience LP, RTP, NC, USA; Report No.: BR 2691; Document No.: M-365179-01-1; March 01, 2010; Pages: 349	830.1550 830.1600 830.1650 830.1750 830.1800 830.6302 830.6303 830.6317 830.7000 830.7100 830.7300	48024601
870 Health Effects Guidelines			
2	Gillissen, U.; BYF 14182 + clothianidin FS 66.5+207 g/L - Acute toxicity in the rat after oral administration; Bayer Schering Pharma AG, Wuppertal, Germany; Report No.: AT05725; Document No.: M-362454-01-2; February 15, 2010; Pages: 29	870.1100	48024602
3	Gillissen, U.; BYF 14182 + clothianidin FS 66.5+207 g/L - Acute toxicity in the rat after dermal application; Bayer Schering Pharma AG, Wuppertal, Germany; Report No.: AT05726; Document No.: M-362456-01-2; February 15, 2010; Pages: 31	870.1200	48024603
4	Folkerts, A.; BYF 14182 + clothianidin FS 66.5+207 g/L - Activity ID TXELP058 - Acute inhalation toxicity in rats; Bayer Schering Pharma AG, Wuppertal, Germany; Report No.: AT05746; Document No.: M-362603-01-2; February 15, 2010; Pages: 76	870.1300	48024604
5	Gmelin, C.; BYF 14182 + clothianidin FS 66.5+207 g/L - Acute eye irritation on rabbits; Bayer Schering Pharma AG, Wuppertal, Germany; Report No.: AT05732; Document No.: M-362457-01-2; February 15, 2010; Pages: 24	870.2400	48024605
6	Gmelin, C.; BYF 14182 + clothianidin FS 66.5+207 g/L - Acute skin irritation/corrosion on rabbits; Bayer Schering Pharma AG, Wuppertal, Germany; Report No.: M-362461-01-2; Document No.: M-362461-01-2; February 15, 2010; Pages: 25	870.2500	48024606
7	Blanck, M.; BYF 14182 + clothianidin FS 66.5+207 g/L - Evaluation of potential skin sensitization in the local lymph node assay in the mouse; Bayer CropScience, Sophia Antipolis, France; Report No.: SA 09342; Document No.: M-362273-01-2; March 04, 2010; Pages: 41	870.2600	48024607
SUPP Studies without Guideline Numbers			
8	Hines, D.; Tier 2 summary of the physical, chemical and technical properties of the plant protection product for Penclo 273.SFS; Bayer CropScience; Report No.: US0014; Document No.: M-365528-01-1; March 13, 2010; Pages: 17	SUPP	48024608
9	Rupprecht, K.; Young, B. M.; Tier 2 summary of the toxicological studies and exposure data and information on the plant protection product for Penclo 273.SFS; Bayer CropScience; Report No.: US0001; Document No.: M-365037-01-1; March 12, 2010; Pages: 25	SUPP	48024609



United States
Environmental Protection Agency
Washington, DC 20460
Formulator's Exemption Statement
(40 CFR 152.85)

Applicant's Name and Address Bayer CropScience 2 T.W. Alexander Drive Research Triangle Park, NC 27709	EPA File Symbol/Registration Number 264-XXXX
	Product Name PENCLO 273.5FS
	Date of Confidential Statement of Formula (EPA Form 8570-4) 02/23/2010

As an authorized representative of the applicant for registration of the product identified above, I certify that:

(1) This product contains the following active ingredient(s):

Penflufen, Clothianidin

(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another person and meets the requirements of 40 CFR section 158.50(e)(2) or (3).

(3) Indicate by checking (A) or (B) below which paragraph applies:

☒ (A) An accurate Confidential Statement of Formula (EPA FORM 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

☐ (B) The Confidential Statement of Formula (CSF)(EPA Form 8570-4) referenced above and on file with the EPA is complete, current, an accurate and contains the information required on the current CSF.

(4) The following active ingredients in this product qualify for the formulator's exemption.

Source		
Active Ingredient	Product Name	Registration Number
Clothianidin		
Product ingredient source information may be entitled to confidential treatment		
Signature	Name and Title Jamin Huang, Registration Manager	Date 03/31/2010

EPA Form 8570-27 (Rev. 06-2004)



M-364942-0111

SUBMISSION
Copy 1: EPA
Copy 2: Applicant copy



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WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060; 2070-0057;
2070-0107; 2070-0122; 2070-01634

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DATA MATRIX

Date: March 31, 2010	EPA Reg. No./File Symbol:	Page 1 of 31
Applicant=s/Registrant=s Name & Address: Bayer CropScience Crop Protection Division 2 T.W. Alexander Drive RTP, North Carolina 27709.	Product(s): PENCLO 273.5FS	
Ingredient: Penflufen, Clothianidin		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.Detail A Product Identity, Composition, and Analysis Test Guidelines (Group A)					
FT			Bayer CropScience (264)	OWN	
CS			Bayer CropScience (264)	OWN	
US			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
830.Detail B.Physical/Chemical Properties Test Guidelines (Group B)					
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
870 Health Effects Guidelines					
			Bayer CropScience (264)	OWN	

Signature	Name and Title: Jamin Huang	Date: March 31, 2010
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EPA Form 8750-35 (12-2003) Electronic Paper versions available. Submit only Paper version.



M-365779-01-1

Public Copy



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2070-0107; 2070-0122; 2070-01634

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DATA MATRIX

Date: March 31, 2010	EPA Reg. No./File Symbol:	Page 2 of 31
Applicant's/Registrant's Name & Address: Bayer CropScience Crop Protection Division 2 T.W. Alexander Drive RTP, North Carolina 27709.	Product(s): PENCLO 273.5FS	
Ingredient: Penflufen, Clothianidin		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
SUPP Studies without Guideline Numbers					
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	

Signature 	Name and Title: Jamin Huang	Date: March 31, 2010
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WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060; 2070-0057;
2070-0107; 2070-0122; 2070-01634

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DATA MATRIX

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Applicant's/Registrant's Name & Address: Bayer CropScience Crop Protection Division 2 T.W. Alexander Drive RTP, North Carolina 27709.	Product(s): PENCLO 273.5FS	
Ingredient: Penflufen, Clothianidin		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
PENFLUFEN TC (Datamatrix)					
830 Series Product Properties					
830.Detail A Group A—Product Identity, Composition, and Analysis Test Guidelines					
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
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			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	

Signature	Name and Title: Jamin Huang	Date: March 31, 2010
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DATA MATRIX

Date: March 31, 2010	EPA Reg. No./File Symbol:	Page 4 of 31
Applicant=Registrant's Name & Address: Bayer CropScience Crop Protection Division 2 T.W. Alexander Drive RTP, North Carolina 27709.	Product(s): PENCLO 273.5FS	
Ingredient: Penflufen, Clothianidin		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	

Signature 	Name and Title: Jamin Huang	Date: March 31, 2010
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DATA MATRIX

Date: March 31, 2010

EPA Reg. No./File Symbol:

Page 5 of 31

Applicant's/Registrant's Name & Address:

Bayer CropScience
Crop Protection Division
2 T.W. Alexander Drive
RTP, North Carolina 27709.

Product(s):
PENCLO 273.5FS

Ingredient: Penflufen, Clothianidin

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830. Detail B Group B—Physical/Chemical Properties Test Guidelines					
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	

Signature

Name and Title:
Jamin Huang

Date: March 31, 2010

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DATA MATRIX

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Ingredient: Penflufen, Clothianidin		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	

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DATA MATRIX

Date: March 31, 2010

EPA Reg. No./File Symbol:

Page 7 of 31

Applicant's/Registrant's Name & Address:

Bayer CropScience
Crop Protection Division
2 T.W. Alexander Drive
RTP, North Carolina 27709.

Product(s):
PENCLO 273.5FS

Ingredient: Penflufen, Clothianidin

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	

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DATA MATRIX

Date: March 31, 2010	EPA Reg. No./File Symbol:	Page 8 of 31
Applicant=Registrant's Name & Address: Bayer CropScience Crop Protection Division 2 T.W. Alexander Drive RTP, North Carolina 27709.	Product(s): PENCLO 273.5FS	
Ingredient: Penflufen, Clothianidin		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
835 Fate, Transport and Transformation					
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	

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DATA MATRIX

Date: March 31, 2010	EPA Reg. No./File Symbol:	Page 9 of 31
Applicant's/Registrant's Name & Address: Bayer CropScience Crop Protection Division 2 T.W. Alexander Drive RTP, North Carolina 27709.	Product(s): PENCLO 273.5FS	
Ingredient: Penflufen, Clothianidin		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
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			Bayer CropScience (264)	OWN	

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DATA MATRIX

Date: March 31, 2010	EPA Reg. No./File Symbol:	Page 10 of 31
Applicant's/Registrant's Name & Address: Bayer CropScience Crop Protection Division 2 T.W. Alexander Drive RTP, North Carolina 27709.	Product(s): PENCLO 273.5FS	
Ingredient: Penflufen, Clothianidin		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
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DATA MATRIX

Date: March 31, 2010

EPA Reg. No./File Symbol:

Page 11 of 31

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Bayer CropScience
Crop Protection Division
2 T.W. Alexander Drive
RTP, North Carolina 27709.

Product(s):
PENCLO 273.5FS

Ingredient: Penflufen, Clothianidin

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
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			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
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DATA MATRIX

Date: March 31, 2010	EPA Reg. No./File Symbol:	Page 12 of 31
Applicant=s/Registrant=s Name & Address: Bayer CropScience Crop Protection Division 2 T.W. Alexander Drive RTP, North Carolina 27709.	Product(s): PENCLO 273.5FS	
Ingredient: Penflufen, Clothianidin		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
850 Ecological Effects Test Guidelines					
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
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			Bayer CropScience (264)	OWN	

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DATA MATRIX

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EPA Reg. No./File Symbol:

Page 13 of 31

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Bayer CropScience
Crop Protection Division
2 T.W. Alexander Drive
RTP, North Carolina 27709.

Product(s):
PENCL0 273.5FS

Ingredient: Penflufen, Clothianidin

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DATA MATRIX

Date: March 31, 2010	EPA Reg. No./File Symbol:	Page 14 of 31
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Ingredient: Penflufen, Clothianidin		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
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			Bayer CropScience (264)	OWN	
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DATA MATRIX

Date: March 31, 2010	EPA Reg. No./File Symbol:	Page 15 of 31
Applicant's/Registrant's Name & Address: Bayer CropScience Crop Protection Division 2 T.W. Alexander Drive RTP, North Carolina 27709.	Product(s): PENCLO 273.5FS	
Ingredient: Penflufen, Clothianidin		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
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DATA MATRIX

Date: March 31, 2010

EPA Reg. No./File Symbol:

Page 16 of 31

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Bayer CropScience
Crop Protection Division
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RTP, North Carolina 27709.

Product(s):
PENCLO 273.5FS

Ingredient: Penflufen, Clothianidin

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
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			Bayer CropScience (264)	OWN	
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DATA MATRIX

Date: March 31, 2010	EPA Reg. No./File Symbol:	Page 17 of 31
Applicant's/Registrant's Name & Address: Bayer CropScience Crop Protection Division 2 T.W. Alexander Drive RTP, North Carolina 27709.	Product(s): PENCLO 273.5FS	
Ingredient: Penflufen, Clothianidin		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
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			Bayer CropScience (264)	OWN	
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DATA MATRIX

Date: March 31, 2010	EPA Reg. No./File Symbol:	Page 18 of 31
Applicant=s/Registrant=s Name & Address: Bayer CropScience Crop Protection Division 2 T.W. Alexander Drive RTP, North Carolina 27709.	Product(s): PENCLO 273.5FS	
Ingredient: Penflufen, Clothianidin		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
860 Residue Chemistry					
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
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			Bayer CropScience (264)	OWN	
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DATA MATRIX

Date: March 31, 2010

EPA Reg. No./File Symbol:

Page 19 of 31

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RTP, North Carolina 27709.

Product(s):
PENCLO 273.5FS

Ingredient: Penflufen, Clothianidin

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			Bayer CropScience (264)	OWN	
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			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	

Signature

Name and Title:
Jamin Huang

Date: March 31, 2010



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DATA MATRIX

Date: March 31, 2010	EPA Reg. No./File Symbol:	Page 20 of 31
Applicant=s/Registrant=s Name & Address: Bayer CropScience Crop Protection Division 2 T.W. Alexander Drive RTP, North Carolina 27709.	Product(s): PENCLO 273.5FS	
Ingredient: Penflufen, Clothianidin		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
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			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
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			Bayer CropScience (264)	OWN	

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DATA MATRIX

Date: March 31, 2010	EPA Reg. No./File Symbol:	Page 21 of 31
Applicant's/Registrant's Name & Address: Bayer CropScience Crop Protection Division 2 T.W. Alexander Drive RTP, North Carolina 27709.	Product(s): PENCLO 273.5FS	
Ingredient: Penflufen, Clothianidin		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
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			Bayer CropScience (264)	OWN	

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DATA MATRIX

Date: March 31, 2010	EPA Reg. No./File Symbol:	Page 22 of 31
Applicant's/Registrant's Name & Address: Bayer CropScience Crop Protection Division 2 T.W. Alexander Drive RTP, North Carolina 27709.	Product(s): PENCLO 273.5FS	
Ingredient: Penflufen, Clothianidin		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
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			Bayer CropScience (264)	OWN	

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DATA MATRIX

Date: March 31, 2010

EPA Reg. No./File Symbol:

Page 23 of 31

Applicant's/Registrant's Name & Address:

Bayer CropScience
Crop Protection Division
2 T.W. Alexander Drive
RTP, North Carolina 27709.

Product(s):
PENCLO 273.5FS

Ingredient: Penflufen, Clothianidin

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	

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DATA MATRIX

Date: March 31, 2010

EPA Reg. No./File Symbol:

Page 24 of 31

Applicant's/Registrant's Name & Address:

Bayer CropScience
Crop Protection Division
2 T.W. Alexander Drive
RTP, North Carolina 27709.

Product(s):
PENCLO 273.5FS

Ingredient: Penflufen, Clothianidin

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	

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DATA MATRIX

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Applicant=s/Registrant=s Name & Address: Bayer CropScience Crop Protection Division 2 T.W. Alexander Drive RTP, North Carolina 27709.	Product(s): PENCLO 273.5FS	
Ingredient: Penflufen, Clothianidin		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870 Health Effects Guidelines					
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
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			Bayer CropScience (264)	OWN	

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DATA MATRIX

Date: March 31, 2010	EPA Reg. No./File Symbol:	Page 26 of 31
Applicant=s/Registrant=s Name & Address: Bayer CropScience Crop Protection Division 2 T.W. Alexander Drive RTP, North Carolina 27709.	Product(s): PENCLO 273.5FS	
Ingredient: Penflufen, Clothianidin		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
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			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
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			Bayer CropScience (264)	OWN	

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EPA Reg. No./File Symbol:

Page 27 of 31

Applicant's/Registrant's Name & Address:

Bayer CropScience
Crop Protection Division
2 T.W. Alexander Drive
RTP, North Carolina 27709.

Product(s):
PENCLO 273.5FS

Ingredient: Penflufen, Clothianidin

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
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Applicant(s)/Registrant(s) Name & Address: Bayer CropScience Crop Protection Division 2 T.W. Alexander Drive RTP, North Carolina 27709.	Product(s): PENCLO 273.5FS	
Ingredient: Penflufen, Clothianidin		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
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Applicant's/Registrant's Name & Address: Bayer CropScience Crop Protection Division 2 T.W. Alexander Drive RTP, North Carolina 27709.	Product(s): PENCLO 273.5FS	
Ingredient: Penflufen, Clothianidin		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
SUPP Supplemental Information					
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
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			Bayer CropScience (264)	OWN	

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DATA MATRIX

EPA Reg. No./File Symbol:

Page 30 of 31

Product(s):
PENCLO 273.5FS

**Bayer CropScience
Crop Protection Division
2 T.W. Alexander Drive
RTP, North Carolina 27709**

Ingredient: Penflufen, Clothianidin

[illegible]

Name and Title:
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Ingredient: Penflufen, Clothianidin		

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			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
			Bayer CropScience (264)	OWN	
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			Bayer CropScience (264)	OWN	

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Ingredient: Penflufen, Clothianidin		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.Detail A Product Identity, Composition, and Analysis Test Guidelines (Group A)					
830.1550	Product Identity and Composition	48024601	Bayer CropScience (264)	OWN	M-365179-01-1 (BR 2691)
830.1600	Description of Material Used to Produce the Product	48024601	Bayer CropScience (264)	OWN	M-365179-01-1 (BR 2691)
830.1650	Description of Formulation Process	48024601	Bayer CropScience (264)	OWN	M-365179-01-1 (BR 2691)
830.1750	Certified Limits	48024601	Bayer CropScience (264)	OWN	M-365179-01-1 (BR 2691)
830.1800	Enforcement Analytical Method	48024601	Bayer CropScience (264)	OWN	M-365179-01-1 (BR 2691)
830.Detail-B:Physical/Chemical Properties Test Guidelines (Group B)					
830.6302	Color	48024601	Bayer CropScience (264)	OWN	M-365179-01-1 (BR 2691)
830.6303	Physical State	48024601	Bayer CropScience (264)	OWN	M-365179-01-1 (BR 2691)
830.6317	Storage Stability	48024601	Bayer CropScience (264)	OWN	M-365179-01-1 (BR 2691)
830.7000	pH of Water Solutions or Suspensions	48024601	Bayer CropScience (264)	OWN	M-365179-01-1 (BR 2691)
830.7100	Viscosity	48024601	Bayer CropScience (264)	OWN	M-365179-01-1 (BR 2691)
830.7300	Density/Relative Density/Bulk Density	48024601	Bayer CropScience (264)	OWN	M-365179-01-1 (BR 2691)
870 Health-Effects Guidelines					
870.1100	Acute Oral Toxicity	48024602	Bayer CropScience (264)	OWN	M-362454-01-2 (AT05725) Lynx Number: TXELP055

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DATA MATRIX

Date: March 31, 2010	EPA Reg. No./File Symbol:	Page 2 of 31
Applicant=Registrant's Name & Address: Bayer CropScience Crop Protection Division 2 T.W. Alexander Drive RTP, North Carolina 27709.	Product(s): PENCLO 273.5FS	
Ingredient: Penflufen, Clothianidin		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.1200	Acute Dermal Toxicity	48024603	Bayer CropScience (264)	OWN	M-362456-01-2 (AT05726) Lynx Number: TXELP057
870.1300	Acute Inhalation Toxicity	48024604	Bayer CropScience (264)	OWN	M-362603-01-2 (AT05746) Lynx Number: TXELP058
870.2400	Acute Eye Irritation	48024605	Bayer CropScience (264)	OWN	M-362457-01-2 (AT05732) Lynx Number: TXELP059
870.2500	Acute Dermal Irritation	48024606	Bayer CropScience (264)	OWN	M-362461-01-2 (M-362461-01-2) Lynx Number: TXELP060
870.2600	Skin Sensitization	48024607	Bayer CropScience (264)	OWN	M-362273-01-2 (SA 09342) Lynx Number: TXELP078
SUPP Studies without Guideline Numbers					
SUPP	Tier 2 Summary - Product Chemistry	48024608	Bayer CropScience (264)	OWN	M-365528-01-1 (US0014)
SUPP	Tier 2 Summary - Toxicology and Exposure Data	48024609	Bayer CropScience (264)	OWN	M-365037-01-1 (US0001)

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EPA Reg. No./File Symbol:

Page 3 of 31

Applicant's/Registrant's Name & Address:

Bayer CropScience
Crop Protection Division
2 T.W. Alexander Drive
RTP, North Carolina 27709.

Product(s):
PENCLO 273.5FS

Ingredient: Penflufen, Clothianidin

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
PENFLUFEN TC (Datamatrix)					
830 Series Product Properties					
830.Detail A Group A—Product Identity, Composition, and Analysis Test Guidelines					
830.1550	Product Identity and Composition	48023501	Bayer CropScience (264)	OWN	M-355379-01-2 (G202113)
830.1600	Description of Material Used to Produce the Product	48023501	Bayer CropScience (264)	OWN	M-355379-01-2 (G202113)
830.1620	Description of Product Process	48023501	Bayer CropScience (264)	OWN	M-355379-01-2 (G202113)
830.1670	Discussion of Formation of Impurities	48023502	Bayer CropScience (264)	OWN	M-355717-01-2 (G202121)
830.1700	Preliminary Analysis	48023503	Bayer CropScience (264)	OWN	M-357231-01-2 (15-920-2456) Lynx Number: TRELPO38
830.1700	Preliminary Analysis for chronic Tox sample and bridging tox	48023504	Bayer CropScience (264)	OWN	M-357266-01-2 (15-920-2457) Lynx Number: TRELPO21
830.1750	Certified Limits	48023503	Bayer CropScience (264)	OWN	M-357231-01-2 (15-920-2456) Lynx Number: TRELPO38
830.1800	Validation of Determination of active substance in technical material	48023505	Bayer CropScience (264)	OWN	M-349499-02-2 (VB1-AM007609MP1) Lynx Number: TRELPO07
830.1800	Validation of IC-method	48023506	Bayer CropScience (264)	OWN	M-351115-01-2 (VB1.1-AM004006MP1) Lynx Number: TRELPO07

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Date: March 31, 2010



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DATA MATRIX

Date: March 31, 2010	EPA Reg. No./File Symbol:	Page 4 of 31
Applicant's/Registrant's Name & Address: Bayer CropScience Crop Protection Division 2 T.W. Alexander Drive RTP, North Carolina 27709.	Product(s): PENCLO 273.5FS	
Ingredient: Penflufen, Clothianidin		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.1800	Validation of AM007709MP2 and AM007809MP2	48023507	Bayer CropScience (264)	OWN	M-356358-01-2 (VB1-AM007709MP2) Lynx Number: TRELPO07
830.SUPP	Determination of by-products in technical material - GC	48023508	Bayer CropScience (264)	OWN	M-347943-02-3 (AM007709MP2)
830.SUPP	Determination of volatile solvents in active ingredient	47372206	Bayer CropScience (264)	OWN	M-088640-01-2 (AM001904MP1)
830.SUPP	Determination of anions and cations in technical grade active substance	47372217	Bayer CropScience (264)	OWN	M-269167-01-2 (AM004006MP1)
830.SUPP	Determination of BCS-AJ73085 and BCS-AK85097 and BCS-AA10598 - GC	48023509	Bayer CropScience (264)	OWN	M-347964-02-3 (AM007809MP2)
830.SUPP	Analytical procedure for the Karl Fischer water determination	47372219	Bayer CropScience (264)	OWN	M-021975-01-3 (2005-0009701-99)
830.SUPP	Validation of GLC-method AM001904MP1 - Determination of volatile solve	48023510	Bayer CropScience (264)	OWN	M-349754-02-2 (VB1.11-AM001904MP1)
830.SUPP	Determination of active substance in technical material GC	48023511	Bayer CropScience (264)	OWN	M-345360-02-3 (AM007609MP2)
830.SUPP	Incineration as a safe means of disposal and pyrolytic behaviour	48023512	Bayer CropScience (264)	OWN	M-354987-01-2 (M-354987-01-2)
830.SUPP	Determination of Inerts	48023513	Bayer CropScience (264)	OWN	M-358067-02-2 (2009/0060/01) Lynx Number: TRELPO40
830.SUPP	1st Addendum to Internal Certificate MZ 00216	48023514	Bayer CropScience (264)	OWN	M-349140-01-3 (M-349140-01-3)

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DATA MATRIX

Date: March 31, 2010

EPA Reg. No./File Symbol:

Page 5 of 31

Applicant's/Registrant's Name & Address:

Bayer CropScience
Crop Protection Division
2 T.W. Alexander Drive
RTP, North Carolina 27709.

Product(s):

PENCLO 273.5FS

Ingredient: Penflufen, Clothianidin

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.SUPP	Toxicological equivalence assessment of the technical specification	48023515	Bayer CropScience (264)	OWN	M-358476-01-2 (G202162)
830.Detail B Group B—Physical/Chemical Properties Test Guidelines					
830.6302	Color	48023516	Bayer CropScience (264)	OWN	M-294189-01-3 (PA07/038) Lynx Number: TRELPO14
830.6302	Color	48023517	Bayer CropScience (264)	OWN	M-351156-01-2 (PA09/047) Lynx Number: TRELPO14
830.6303	Physical State	48023516	Bayer CropScience (264)	OWN	M-294189-01-3 (PA07/038) Lynx Number: TRELPO14
830.6303	Physical State	48023517	Bayer CropScience (264)	OWN	M-351156-01-2 (PA09/047) Lynx Number: TRELPO14
830.6304	Odor	48023516	Bayer CropScience (264)	OWN	M-294189-01-3 (PA07/038) Lynx Number: TRELPO14
830.6304	Odor	48023517	Bayer CropScience (264)	OWN	M-351156-01-2 (PA09/047) Lynx Number: TRELPO14
830.6313	Stability to Normal and Elevated Temperatures, Metals, and Metal I...	48023518	Bayer CropScience (264)	OWN	M-352469-01-2 (15-160-2424) Lynx Number: TRELPO32
830.6314	Oxidation/Reduction: Chemical Incompatibility	48023519	Bayer CropScience (264)	OWN	M-351154-01-2 (PA09/046) Lynx Number: TRELPO14

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DATA MATRIX

Date: March 31, 2010	EPA Reg. No./File Symbol:	Page 6 of 31
Applicant's/Registrant's Name & Address: Bayer CropScience Crop Protection Division 2 T.W. Alexander Drive RTP, North Carolina 27709.	Product(s): PENCLO 273.5FS	
Ingredient: Penflufen, Clothianidin		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6315	Flammability	48023520	Bayer CropScience (264)	OWN	M-352113-01-2 (20090376.07) Lynx Number: TRELPO22
830.6316	Explosibility	48023521	Bayer CropScience (264)	OWN	M-352100-01-2 (20090376.03) Lynx Number: TRELPO16
830.6317	Storage Stability	48023522	Bayer CropScience (264)	OWN	M-358081-02-2 (15-155-2359) Lynx Number: TRELPO24
830.6319	Miscibility	48023523	Bayer CropScience (264)	OWN	M-352798-01-2 (AF09/053) Lynx Number: TRELPO14
830.6320	Corrosion Characteristics	48023518	Bayer CropScience (264)	OWN	M-352469-01-2 (15-160-2424) Lynx Number: TRELPO32
830.6321	Dielectric Breakdown Voltage	48023524	Bayer CropScience (264)	OWN	M-352800-01-2 (AF09/054) Lynx Number: TRELPO14
830.7000	pH of Water Solutions or Suspensions	48023525	Bayer CropScience (264)	OWN	M-294186-01-3 (PA07/036) Lynx Number: TRELPO14
830.7050	UV/Visible Absorption	48023526	Bayer CropScience (264)	OWN	M-349505-02-2 (M-349505-02-2) Lynx Number: TRELPO18
830.7100	Viscosity	48023527	Bayer CropScience (264)	OWN	M-352803-01-2 (AF09/055) Lynx Number: TRELPO14
830.7200	Melting Point/Melting Range	48023528	Bayer CropScience (264)	OWN	M-292135-02-2 (20070675.01) Lynx Number: TRELPO14

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DATA MATRIX

Date: March 31, 2010

EPA Reg. No./File Symbol:

Page 7 of 31

Applicant's/Registrant's Name & Address:

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RTP, North Carolina 27709.

Product(s):
PENCLO 273.5FS

Ingredient: Penflufen, Clothianidin

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.7200	Melting Point/Melting Range	48023529	Bayer CropScience (264)	OWN	M-352097-01-2 (20090376.01) Lynx Number: TRELPO14
830.7220	Boiling Point/Boiling Range	48023528	Bayer CropScience (264)	OWN	M-292135-02-2 (20070675.01) Lynx Number: TRELPO14
830.7220	Boiling Point/Boiling Range	48023529	Bayer CropScience (264)	OWN	M-352097-01-2 (20090376.01) Lynx Number: TRELPO14
830.7300	Density/Relative Density/Bulk Density	48023530	Bayer CropScience (264)	OWN	M-299655-01-3 (PA07/035) Lynx Number: TRELPO14
830.7300	Density/Relative Density/Bulk Density	48023531	Bayer CropScience (264)	OWN	M-351151-01-2 (PA09/043) Lynx Number: TRELPO14
830.7370	Dissociation Constants in Water	48023532	Bayer CropScience (264)	OWN	M-352094-01-2 (PA09/059) Lynx Number: TRELPO14
830.7520	Particle Size, Fiber, Length, and Diameter, Distribution	48023533	Bayer CropScience (264)	OWN	M-352108-01-2 (20090376.06) Lynx Number: TRELPO14
830.7570	Partition Coefficient (n-octanol/water). Estimation by Liquid Chro...	48023534	Bayer CropScience (264)	OWN	M-351251-01-2 (PA07/012) Lynx Number: TRELPO14
830.7840	Water Solubility. Column Elution Method; Shake Flask Method	48023535	Bayer CropScience (264)	OWN	M-351057-01-2 (PA07/013) Lynx Number: TRELPO14
830.7840	Water Solubility. Column Elution Method; Shake Flask Method	48023536	Bayer CropScience (264)	OWN	M-351150-01-2 (PA07/037) Lynx Number: TRELPO14

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Date: March 31, 2010	EPA Reg. No./File Symbol:	Page 8 of 31
Applicant=s/Registrant=s Name & Address: Bayer CropScience Crop Protection Division 2 T.W. Alexander Drive RTP, North Carolina 27709.	Product(s): PENCLO 273.5FS	
Ingredient: Penflufen, Clothianidin		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.7950	Vapor Pressure	48023537	Bayer CropScience (264)	OWN	M-292138-02-2 (20070675.02) Lynx Number: TRELPO14
830.SUPP	Determination of the surface tension	48023538	Bayer CropScience (264)	OWN	M-351063-01-2 (PA09/044) Lynx Number: TRELPO14
830.SUPP	Calculation of the Henry's law constant	48023539	Bayer CropScience (264)	OWN	M-352794-01-2 (AF08/008) Lynx Number: TRELPO14
830.SUPP	Oxidizing properties	48023540	Bayer CropScience (264)	OWN	M-352107-01-2 (20090376.05) Lynx Number: TRELPO17
830.SUPP	Flammability (solids)	48023541	Bayer CropScience (264)	OWN	M-352099-01-2 (20090376.02) Lynx Number: TRELPO23
830.SUPP	Auto - flammability (relative self-ignition temperature of solids)	48023542	Bayer CropScience (264)	OWN	M-352101-01-2 (20090376.04) Lynx Number: TRELPO23
830.SUPP	Complex formation ability in water	48023543	Bayer CropScience (264)	OWN	M-351981-01-2 (B 007/2009) Lynx Number: TRELPO42
835 Fate, Transport and Transformation					
835.1220	Sediment and Soil Adsorption/Desorption Isotherm (3-hydroxy-butyl)	48023544	Bayer CropScience (264)	OWN	M-294145-01-2 (AS31) Lynx Number: MEELPO17
835.1220	Sediment and Soil Adsorption/Desorption Isotherm (pyrazolyl-AAP)	48023545	Bayer CropScience (264)	OWN	M-356025-01-2 (MEF-09/155) Lynx Number: MEELPO81

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Date: March 31, 2010	EPA Reg. No./File Symbol:	Page 9 of 31
Applicant=s/Registrant=s Name & Address: Bayer CropScience Crop Protection Division 2 T.W. Alexander Drive RTP, North Carolina 27709.	Product(s): PENCLO 273.5FS	
Ingredient: Penflufen, Clothianidin		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
835.1260	Leaching and Adsorption/Desorption Studies	48023546	Bayer CropScience (264)	OWN	M-274906-01-2 (MEF-05/430) Lynx Number: MEELX005
835.2120	Hydrolysis of Parent and Degradates as a Function of pH at 25 C	48023547	Bayer CropScience (264)	OWN	M-304941-01-2 (MEF-07/480) Lynx Number: MEELP029
835.2240	Phototransformation in aqueous buffer	48023548	Bayer CropScience (264)	OWN	M-354944-01-2 (MEF-09/122) Lynx Number: MEELP028 Lynx Number: MEELP025
835.2240	Photolysis in Natural Water	48023549	Bayer CropScience (264)	OWN	M-355112-02-2 (MEF-09/254) Lynx Number: MEELP041 Lynx Number: MEELP031
835.2370	Quantum yield	48023550	Bayer CropScience (264)	OWN	M-351709-01-2 (MEF-09/219) Lynx Number: MEELP072
835.2370	Calculation of the Chemical Lifetime in the Troposphere	48023551	Bayer CropScience (264)	OWN	M-356310-01-2 (MEF-09/659) Lynx Number: MEELP073
835.4100	Time dependent sorption in soils	48023552	Bayer CropScience (264)	OWN	M-286655-02-2 (MEF-06/546) Lynx Number: MEELP022
835.4100	Aerobic soil metabolism and degradation rate in 2 US soils (label 1&2)	48023553	Bayer CropScience (264)	OWN	M-355977-01-1 (MEELP001) Lynx Number: MEELP001
835.4100	Aerobic soil degradation rate (3 soils) (metabolite)	48023554	Bayer CropScience (264)	OWN	M-353138-01-2 (MEF-09/466) Lynx Number: MEELP089

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DATA MATRIX

Date: March 31, 2010	EPA Reg. No./File Symbol:	Page 10 of 31
Applicant's/Registrant's Name & Address: Bayer CropScience Crop Protection Division 2 T.W. Alexander Drive RTP, North Carolina 27709.	Product(s): PENCLO 273.5FS	
Ingredient: Penflufen, Clothianidin		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
835.4200	Anaerobic Soil Metabolism	48023555	Bayer CropScience (264)	OWN	M-302411-01-2 (MEF-08/043) Lynx Number: MEELP030
835.4300	Aerobic Aquatic Metabolism	48023556	Bayer CropScience (264)	OWN	M-301534-02-2 (MEF-07/468) Lynx Number: MEELP027
835.4400	Anaerobic Aquatic Metabolism	48023557	Bayer CropScience (264)	OWN	M-326979-01-1 (MEELP008) Lynx Number: MEELP008 Lynx Number: MEELP032
835.6100	Terrestrial Field Dissipation (California)	48023558	Bayer CropScience (264)	OWN	M-365080-01-1 (MEELP055) Lynx Number: MEELP055
835.6100	Terrestrial Field Dissipation (Georgia)	48023559	Bayer CropScience (264)	OWN	M-365083-01-1 (MEELP056) Lynx Number: MEELP056
835.6100	Terrestrial Field Dissipation (Idaho)	48023560	Bayer CropScience (264)	OWN	M-365076-01-1 (MEELP026) Lynx Number: MEELP026
835.6100	Terrestrial Field Dissipation (Ontario)	48023561	Bayer CropScience (264)	OWN	M-365077-01-1 (MEELP053) Lynx Number: MEELP053
835.6100	Terrestrial Field Dissipation (Saskatchewan)	48023562	Bayer CropScience (264)	OWN	M-365064-01-1 (MEELP057) Lynx Number: MEELP057
835.6100	Terrestrial Field Dissipation (Prince Edward Island)	48023563	Bayer CropScience (264)	OWN	M-365079-01-1 (MEELP054) Lynx Number: MEELP054

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DATA MATRIX

Date: March 31, 2010	EPA Reg. No./File Symbol:	Page 11 of 31
Applicant=s/Registrant=s Name & Address: Bayer CropScience Crop Protection Division 2 T.W. Alexander Drive RTP, North Carolina 27709.	Product(s): PENCLO 273.5FS	
Ingredient: Penflufen, Clothianidin		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
835.6100	Terrestrial Field Dissipation (Europe)	48023564	Bayer CropScience (264)	OWN	M-350568-01-2 (RA-2147/06) Lynx Number: MEELP021
835.6200	Aquatic (Sediment) Field Dissipation (Cropped Arkansas Rice Field)	48023565	Bayer CropScience (264)	OWN	M-365281-01-1 (RAELP039) Lynx Number: RAELP039
835.SUPP	Kinetic evaluation of the aerobic soil metabolism (Trigger Endpoints)	48023566	Bayer CropScience (264)	OWN	M-291508-01-2 (MEF-07/305) Lynx Number: MEELP060
835.SUPP	Kinetic evaluation of the aerobic soil metabolism (modelling endpoints)	48023567	Bayer CropScience (264)	OWN	M-291516-02-2 (MEF-07/304) Lynx Number: MEELP060
835.SUPP	Kinetic evaluation of the aerobic soil metabolism (2US Soils)	48023568	Bayer CropScience (264)	OWN	M-357337-01-2 (MEF-09/385)
835.SUPP	Supp of Kinetic evaluation of the aerobic soil metabolism (2US Soils)	48023569	Bayer CropScience (264)	OWN	M-356839-01-2 (MEF-09/682) Lynx Number: MEELP109
835.SUPP	Evaluation and standardization field dissipation trials	48023570	Bayer CropScience (264)	OWN	M-356577-01-2 (MEF-09/391) Lynx Number: MEELP061
835.SUPP	Evaluation and standardization field dissipation trials	48023571	Bayer CropScience (264)	OWN	M-356554-01-2 (MEF-09/408) Lynx Number: MEELP061
835.SUPP	Evaluation soil degradation (labdata)	48023572	Bayer CropScience (264)	OWN	M-295252-01-2 (MEF-07/331) Lynx Number: MEELP060
835.SUPP	Kinetic evaluation of the aerobic aquatic metabolism	48023573	Bayer CropScience (264)	OWN	M-302742-01-2 (MEF-08/254) Lynx Number: MEELP059

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DATA MATRIX

Date: March 31, 2010	EPA Reg. No./File Symbol:	Page 12 of 31
Applicant=s/Registrant=s Name & Address: Bayer CropScience Crop Protection Division 2 T.W. Alexander Drive RTP, North Carolina 27709.	Product(s): PENCLO 273.5FS	
Ingredient: Penflufen, Clothianidin		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
850 Ecological Effects Test Guidelines					
850.1010	Aquatic Invert. Acute Toxicity (Daphnids)	48023574	Bayer CropScience (264)	OWN	M-296362-01-1 (EBELP005) Lynx Number: EBELP005
850.1010	Aquatic Invert. Acute Toxicity (Daphnids), Penflufen-3-hydroxy-butyl	48023575	Bayer CropScience (264)	OWN	M-346259-01-1 (EBELP027) Lynx Number: EBELP027
850.1010	Aquatic Invert. Acute Toxicity (Daphnids), Penflufen-pyrazolyl-AAP	48023576	Bayer CropScience (264)	OWN	M-357192-01-2 (EBELP102) Lynx Number: EBELP102
850.1010	Aquatic Invert. Acute Toxicity (crayfish)	48023577	Bayer CropScience (264)	OWN	M-350813-01-1 (EBELP047) Lynx Number: EBELP047
850.1025	Oyster Acute Toxicity Test (Shell Deposition)	48023578	Bayer CropScience (264)	OWN	M-343505-01-1 (EBELP014) Lynx Number: EBELP014
850.1035	Mysid acute toxicity test	48023579	Bayer CropScience (264)	OWN	M-303018-01-1 (EBELP012) Lynx Number: EBELP012
850.1075	Fish Acute Toxicity Test (rainbow trout)	48023580	Bayer CropScience (264)	OWN	M-343491-01-1 (EBELP002) Lynx Number: EBELP002
850.1075	Fish Acute Toxicity Test (bluegill)	48023581	Bayer CropScience (264)	OWN	M-343846-01-1 (EBELP037) Lynx Number: EBELP037
850.1075	Fish Acute Toxicity Test (fathead minnow)	48023582	Bayer CropScience (264)	OWN	M-346776-01-1 (EBELP026) Lynx Number: EBELP026

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Page 13 of 31

Applicant's/Registrant's Name & Address:

Bayer CropScience
Crop Protection Division
2 T.W. Alexander Drive
RTP, North Carolina 27709.

Product(s):
PENCLO 273.5FS

Ingredient: Penflufen. Clothianidin

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
850.1075	Fish Acute Toxicity Test (Cyprinus carpio)	48023583	Bayer CropScience (264)	OWN	M-344774-01-2 (EBELP077) Lynx Number: EBELP077
850.1075	Fish Acute Toxicity Test (Cyprinus carpio), Penflufen-3-hydroxy-butyl	48023584	Bayer CropScience (264)	OWN	M-357272-01-2 (EBELP039) Lynx Number: EBELP039
850.1075	Fish Acute Toxicity Test (Cyprinus carpio), Penflufen-pyrazolyl-AAP	48023585	Bayer CropScience (264)	OWN	M-357274-01-2 (EBELP103) Lynx Number: EBELP103
850.1075	Fish Acute Toxicity Test (sheepshead minnow)	48023586	Bayer CropScience (264)	OWN	M-343499-01-1 (EBELP003) Lynx Number: EBELP003
850.1300	Daphnid Chronic Toxicity Test	48023587	Bayer CropScience (264)	OWN	M-328667-02-1 (EBELP006-1) Lynx Number: EBELP006
850.1400	Fish Early-life Stage Toxicity Test	48023588	Bayer CropScience (264)	OWN	M-329464-01-1 (EBELP004) Lynx Number: EBELP004
850.1730	Fish BCF	48023589	Bayer CropScience (264)	OWN	M-356580-01-2 (MEF-09/100) Lynx Number: MEELP062
850.1735	Whole Sediment: Acute Freshwater Invertebrates	48023590	Bayer CropScience (264)	OWN	M-353945-01-1 (EBELP011) Lynx Number: EBELP011
850.2100	Avian Acute Oral (Northern bobwhite quail)	48023591	Bayer CropScience (264)	OWN	M-357031-01-1 (EBELP015) Lynx Number: EBELP015
850.2100	Avian Acute Oral (canary)	48023592	Bayer CropScience (264)	OWN	M-361570-02-1 (EBELL004-1) Lynx Number: EBELL004

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Date: March 31, 2010	EPA Reg. No./File Symbol:	Page 14 of 31
Applicant=s/Registrant=s Name & Address: Bayer CropScience Crop Protection Division 2 T.W. Alexander Drive RTP, North Carolina 27709.	Product(s): PENCLO 273.5FS	
Ingredient: Penflufen, Clothianidin		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
850.2200	Avian Dietary (Northern bobwhite quail)	48023593	Bayer CropScience (264)	OWN	M-358055-01-1 (EBELP017) Lynx Number: EBELP017
850.2200	Avian Dietary (mallard duck)	48023594	Bayer CropScience (264)	OWN	M-348230-01-1 (EBELP018) Lynx Number: EBELP018
850.2300	Avian Reproduction (Northern bobwhite quail)	48023595	Bayer CropScience (264)	OWN	M-358260-01-1 (EBELP019) Lynx Number: EBELP019
850.2300	Avian Reproduction (mallard duck)	48023596	Bayer CropScience (264)	OWN	M-358529-01-1 (EBELP020) Lynx Number: EBELP020
850.3020	Honey Bee Acute Contact Toxicity	48023597	Bayer CropScience (264)	OWN	M-292797-01-2 (36581035) Lynx Number: EBELP021
850.4100	Terrestrial Plant Toxicity, Tier 1 (Seeding Emergence) (240FS)	48023598	Bayer CropScience (264)	OWN	M-353590-01-2 (SE08 / 005) Lynx Number: EBELP045
850.4100	Terrestrial Plant Toxicity, Tier 1 (Seeding Emergence) (50FS)	48023599	Bayer CropScience (264)	OWN	M-348694-01-2 (SE09/013) Lynx Number: EBELP152
850.4150	Terrestrial Plant Toxicity, Tier 1 (Vegetative Vigor) (240FS)	48023601	Bayer CropScience (264)	OWN	M-353600-01-2 (VV08 / 006) Lynx Number: EBELP046
850.4150	Terrestrial Plant Toxicity, Tier 1 (Vegetative Vigor) (50FS) EU	48023602	Bayer CropScience (264)	OWN	M-348690-01-2 (VV09/014) Lynx Number: EBELP151
850.4400	Aquatic Plant Toxicity Test using Lemna spp. Tiers I and II	48023603	Bayer CropScience (264)	OWN	M-343501-01-1 (EBELP038) Lynx Number: EBELP038

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Date: March 31, 2010	EPA Reg. No./File Symbol:	Page 15 of 31
Applicant's/Registrant's Name & Address: Bayer CropScience Crop Protection Division 2 T.W. Alexander Drive RTP, North Carolina 27709.	Product(s): PENCLO 273.5FS	
Ingredient: Penflufen, Clothianidin		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
850.4500	Aquatic Plant Growth -Algae	48023604	Bayer CropScience (264)	OWN	M-295850-01-1 (EBELP007) Lynx Number: EBELP007
850.4500	Aquatic Plant Growth -Algae, Penflufen-3-hydroxy-butyl	48023605	Bayer CropScience (264)	OWN	M-347970-01-1 (EBELP028) Lynx Number: EBELP028
850.4500	Aquatic Plant Growth -Algae, Penflufen-pyrazolyl-AAP	48023606	Bayer CropScience (264)	OWN	M-346267-02-2 (EBELP101) Lynx Number: EBELP101
850.SUPP	Toxicity to the parasitoid wasp (240FS)	48023607	Bayer CropScience (264)	OWN	M-311401-01-2 (CW08/040) Lynx Number: EBELP068
850.SUPP	Toxicity to the parasitoid wasp (50FS) EU	48023608	Bayer CropScience (264)	OWN	M-346081-01-2 (CW09/009) Lynx Number: EBELP148
850.SUPP	Toxicity to the predatory mite (240FS)	48023609	Bayer CropScience (264)	OWN	M-311411-01-2 (CW08/039) Lynx Number: EBELP069
850.SUPP	Toxicity to the predatory mite (50FS) EU	48023610	Bayer CropScience (264)	OWN	M-349193-01-2 (CW09/008) Lynx Number: EBELP147
850.SUPP	Acute toxicity to earthworms	48023611	Bayer CropScience (264)	OWN	M-294423-01-2 (LRT/RG-A-95/07) Lynx Number: EBELP023
850.SUPP	Sublethal Effects on earthworm (240FS)	48023612	Bayer CropScience (264)	OWN	M-295772-01-2 (LRT-RG-R-40/07) Lynx Number: EBELP042
850.SUPP	Sublethal Effects on earthworm (Penflufen-3-hydroxy-butyl)	48023613	Bayer CropScience (264)	OWN	M-304291-01-2 (LRT-RG-R-48/08) Lynx Number: EBELP030

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Date: March 31, 2010	EPA Reg. No./File Symbol:	Page 16 of 31
Applicant=s/Registrant=s Name & Address: Bayer CropScience Crop Protection Division 2 T.W. Alexander Drive RTP, North Carolina 27709.	Product(s): PENCLO 273.5FS	
Ingredient: Penflufen, Clothianidin		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
850.SUPP	Sublethal Effects on earthworm (Penflufen-pyrazolyl-AAP)	48023614	Bayer CropScience (264)	OWN	M-349225-01-2 (09 10 48 033 S) Lynx Number: EBELP100
850.SUPP	Sublethal Effects on earthworm (50FS) EU	48023615	Bayer CropScience (264)	OWN	M-354676-01-2 (LRT-RG-R-58/09) Lynx Number: EBELP073
850.SUPP	Nitrogen Transformation	48023616	Bayer CropScience (264)	OWN	M-329923-01-2 (LRT-N-112/09) Lynx Number: EBELP098
850.SUPP	Nitrogen Transformation (Penflufen-3-hydroxy-butyI)	48023617	Bayer CropScience (264)	OWN	M-345431-01-2 (LRT-N-116/09) Lynx Number: EBELP035
850.SUPP	Nitrogen Transformation (Penflufen-pyrazolyl-AAP)	48023618	Bayer CropScience (264)	OWN	M-345424-01-2 (LRT-N-115/09) Lynx Number: EBELP105
850.SUPP	Carbon Transformation	48023619	Bayer CropScience (264)	OWN	M-341294-01-2 (LRT-C-97/09) Lynx Number: EBELP097
850.SUPP	Carbon Transformation (Penflufen-3-hydroxy-butyI)	48023620	Bayer CropScience (264)	OWN	M-344744-01-2 (LRT-C-101/09) Lynx Number: EBELP139
850.SUPP	Carbon Transformation (Penflufen-pyrazolyl-AAP)	48023621	Bayer CropScience (264)	OWN	M-344691-01-2 (LRT-C-100/09) Lynx Number: EBELP141
850.SUPP	Inhibition of fungal growth by Penflufen-3-hydroxy-butyI	48023622	Bayer CropScience (264)	OWN	M-295764-01-2 (VAR 2007-02) Lynx Number: EBELP034
850.SUPP	Inhibition of fungal growth by Penflufen-pyrazolyl-AAP	48023623	Bayer CropScience (264)	OWN	M-351174-01-2 (BNJ 2009-01) Lynx Number: EBELP154

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Applicant's/Registrant's Name & Address:	Product(s):	
Bayer CropScience Crop Protection Division 2 T.W. Alexander Drive RTP, North Carolina 27709.	PENCLO 273.5FS	
Ingredient: Penflufen, Clothianidin		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
850.SUPP	Toxicity to bacteria	48023624	Bayer CropScience (264)	OWN	M-289933-01-2 (2007/0064/01) Lynx Number: EBELP022
850.SUPP	Influence on collembola species (240FS)	48023625	Bayer CropScience (264)	OWN	M-291241-01-2 (FRM-COLL-56/07) Lynx Number: EBELP043
850.SUPP	Influence on soil mite (240FS)	48023626	Bayer CropScience (264)	OWN	M-294547-01-2 (KRA-HR-5/07) Lynx Number: EBELP044
850.SUPP	Influence on collembola species (Penflufen-3-hydroxy-butyl)	48023627	Bayer CropScience (264)	OWN	M-348154-01-2 (FRM-COLL-72/09) Lynx Number: EBELP031
850.SUPP	Influence on soil mite (Penflufen-3-hydroxy-butyl)	48023628	Bayer CropScience (264)	OWN	M-329899-01-2 (KRA-HR-14/09) Lynx Number: EBELP032
850.SUPP	Influence on collembola species (Penflufen-pyrazolyl-AAP)	48023629	Bayer CropScience (264)	OWN	M-348117-01-2 (FRM-COLL-73/09) Lynx Number: EBELP140
850.SUPP	Influence on soil mite (Penflufen-pyrazolyl-AAP)	48023630	Bayer CropScience (264)	OWN	M-329902-01-2 (KRA-HR-13/09) Lynx Number: EBELP106
850.SUPP	Influence on collembola species (50FS)	48023631	Bayer CropScience (264)	OWN	M-344200-01-2 (FRM-COLL-70/09) Lynx Number: EBELP072
850.SUPP	Influence on soil mite (50FS)	48023632	Bayer CropScience (264)	OWN	M-329498-01-2 (KRA-HR-12/09) Lynx Number: EBELP071
850.SUPP	Impacts on soil litter degradation	48023633	Bayer CropScience (264)	OWN	M-357343-01-2 (LRT-SLD-39/09) Lynx Number: EBELP036

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Date: March 31, 2010	EPA Reg. No./File Symbol:	Page 18 of 31
Applicant=Registrant's Name & Address: Bayer CropScience Crop Protection Division 2 T.W. Alexander Drive RTP, North Carolina 27709.	Product(s): PENCLO 273.5FS	
Ingredient: Penflufen, Clothianidin		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
860 Residue Chemistry					
860.1300	Plant Metabolism (potato, pyrazole label)	48023634	Bayer CropScience (264)	OWN	M-350696-01-2 (MEF-08/262) Lynx Number: MEELP004
860.1300	Plant Metabolism (potato, phenyl label)	48023635	Bayer CropScience (264)	OWN	M-346321-01-2 (MEF-08/420) Lynx Number: MEELP005
860.1300	Plant Metabolism (wheat, pyrazole label)	48023636	Bayer CropScience (264)	OWN	M-355232-01-2 (MEF-09/404) Lynx Number: MEELP023
860.1300	Plant Metabolism (wheat, phenyl label)	48023637	Bayer CropScience (264)	OWN	M-355837-01-2 (MEF-09/422) Lynx Number: MEELP024
860.1300	Plant Metabolism (soybean, pyrazole label)	48023638	Bayer CropScience (264)	OWN	M-352684-01-2 (MEF-09/258) Lynx Number: MEELP019
860.1300	Plant Metabolism (soybean, phenyl label)	48023639	Bayer CropScience (264)	OWN	M-351743-01-2 (MEF-09/323) Lynx Number: MEELP018
860.1300	Plant Metabolism (paddy rice, pyrazole label)	48023640	Bayer CropScience (264)	OWN	M-351446-01-2 (MEF-09/126) Lynx Number: MEELP013
860.1300	Plant Metabolism (paddy rice, phenyl label)	48023641	Bayer CropScience (264)	OWN	M-352182-01-2 (MEF-09/127) Lynx Number: MEELP012
860.1300	Determination of the TRR, sunflower (label 1)	48023642	Bayer CropScience (264)	OWN	M-296493-01-1 (MEELP043) Lynx Number: MEELP043

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Page 19 of 31

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Bayer CropScience
Crop Protection Division
2 T.W. Alexander Drive
RTP, North Carolina 27709.

Product(s):
PENCLO 273.5FS

Ingredient: Penflufen, Clothianidin

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
860.1300	Determination of the TRR, corn (label 1)	48023643	Bayer CropScience (264)	OWN	M-296646-02-1 (MEELP045-1) Lynx Number: MEELP045
860.1300	Determination of the TRR, cotton (label 1), 2 rates	48023644	Bayer CropScience (264)	OWN	M-296645-02-1 (MEELP047-1) Lynx Number: MEELP047
860.1300	Determination of the TRR, canola (label 1)	48023645	Bayer CropScience (264)	OWN	M-295916-01-1 (MEELP049) Lynx Number: MEELP049
860.1300	Determination of the TRR, Edible podded legumes, crop group 6A	48023646	Bayer CropScience (264)	OWN	M-357722-01-1 (MEELP079) Lynx Number: MEELP079
860.1300	Determination of the TRR, Succulent peas and beans, crop group 6B	48023647	Bayer CropScience (264)	OWN	M-356467-01-1 (MEELP080) Lynx Number: MEELP080
860.1300	Determination of the TRR, alfalfa	48023648	Bayer CropScience (264)	OWN	M-363667-02-1 (MEELP110-1) Lynx Number: MEELP110
860.1300	Laying Hen Metabolism (label 1, phenyl)	48023649	Bayer CropScience (264)	OWN	M-346752-01-2 (MEF-08/206) Lynx Number: MEELP038
860.1300	Laying Hen Metabolism (label 2, pyrazole)	48023650	Bayer CropScience (264)	OWN	M-347508-01-2 (MEF-08/207) Lynx Number: MEELP037
860.1300	Dairy Goat Metabolism (label 1, phenyl)	48023701	Bayer CropScience (264)	OWN	M-350779-01-2 (MEF-08/204) Lynx Number: MEELP040
860.1300	Dairy Goat Metabolism (label 2, pyrazole)	48023702	Bayer CropScience (264)	OWN	M-356120-01-2 (MEF-08/205) Lynx Number: MEELP039

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Date: March 31, 2010	EPA Reg. No./File Symbol:	Page 20 of 31
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Ingredient: Penflufen, Clothianidin		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
860.1340	Residue Method - Plant	48023703	Bayer CropScience (264)	OWN	M-352691-02-2 (MR-08/177) Lynx Number: RAELP010
860.1340	Radio validation (accountability) of rotational crop method	48023704	Bayer CropScience (264)	OWN	M-355707-01-2 (MEF-09/448) Lynx Number: RAELP014
860.1340	Method for plants (enforcement)	48023705	Bayer CropScience (264)	OWN	M-347695-01-2 (P/B 1665G) Lynx Number: RAELP023
860.1340	Independent lab validation for plants (enforcement)	48023706	Bayer CropScience (264)	OWN	M-356500-01-2 (P/B 1753 G) Lynx Number: RAELP022
860.1340	US data-gathering method	48023707	Bayer CropScience (264)	OWN	M-364625-01-1 (EL-002-P09-02) Lynx Number: RAELP008
860.1340	US data-gathering method 2	48023708	Bayer CropScience (264)	OWN	M-365068-01-1 (EL-002-P09-03) Lynx Number: RAELP008
860.1340	Independent lab validation plant	48023709	Bayer CropScience (264)	OWN	M-365069-01-1 (RAELP092) Lynx Number: RAELP092
860.1340	Multi-residue testing of all enforcement targets	48023710	Bayer CropScience (264)	OWN	M-364940-01-2 (RAELP075) Lynx Number: RAELP075
860.1340	Biota Method	48023711	Bayer CropScience (264)	OWN	M-365105-01-2 (01192) Lynx Number: RAELP028
860.1340	Method for soil (data generation) + validation sediment	48023712	Bayer CropScience (264)	OWN	M-307331-01-2 (MR-08/123) Lynx Number: RAELP070

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DATA MATRIX

Date: March 31, 2010

EPA Reg. No./File Symbol:

Page 21 of 31

Applicant's/Registrant's Name & Address:

Bayer CropScience
Crop Protection Division
2 T.W. Alexander Drive
RTP, North Carolina 27709.

Product(s):
PENCLO 273.5FS

Ingredient: Penflufen, Clothianidin

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
860.1340	Method for soil (enforcement)	48023713	Bayer CropScience (264)	OWN	M-349415-01-2 (01153) Lynx Number: RAELP034
860.1340	Independent lab validation for soil (enforcement)	48023714	Bayer CropScience (264)	OWN	M-356808-01-1 (RAELP007) Lynx Number: RAELP007
860.1340	NAFTA Water Method	48023715	Bayer CropScience (264)	OWN	M-365072-01-1 (EL-001-W08-02) Lynx Number: RAELP029#0
860.1340	Method for water (data generation)	48023716	Bayer CropScience (264)	OWN	M-365075-01-1 (RAELP013) Lynx Number: RAELP013
860.1340	Method for water (enforcement)	48023717	Bayer CropScience (264)	OWN	M-350548-01-2 (M-350548-01-2) Lynx Number: RAELP033
860.1340	Independent lab validation for water (enforcement, US)	48023718	Bayer CropScience (264)	OWN	M-360734-01-2 (EL-001-W08-01) Lynx Number: RAELP063
860.1360	Multi-residue testing of all enforcement targets	48023710	Bayer CropScience (264)	OWN	M-364940-01-2 (RAELP075) Lynx Number: RAELP075
860.1380	Determination of the storage stability	48023719	Bayer CropScience (264)	OWN	M-358296-01-2 (MR-09/156) Lynx Number: RAELP002
860.1380	Storage stability	48023720	Bayer CropScience (264)	OWN	M-349051-01-2 (MEF-09/056) Lynx Number: MEELP090
860.1380	Storage stability plant matrices	48023721	Bayer CropScience (264)	OWN	M-357586-01-2 (08-16) Lynx Number: RAELP009

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DATA MATRIX

Date: March 31, 2010	EPA Reg. No./File Symbol:	Page 22 of 31
Applicant's/Registrant's Name & Address: Bayer CropScience Crop Protection Division 2 T.W. Alexander Drive RTP, North Carolina 27709.	Product(s): PENCLO 273.5FS	
Ingredient: Penflufen, Clothianidin		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
860.1380	Storage stability water (active substance and metabolites)	48023722	Bayer CropScience (264)	OWN	M-365071-01-1 (RAELP062) Lynx Number: RAELP062
860.1480	Meat/Milk/Poultry/Eggs	48023723	Bayer CropScience (264)	OWN	M-364953-01-1 (RAELP030) Lynx Number: RAELP030
860.1500	Residues in/on Wheat	48023724	Bayer CropScience (264)	OWN	M-364819-01-1 (RAELP049) Lynx Number: RAELP049
860.1500	Residues In/On Barley	48023725	Bayer CropScience (264)	OWN	M-364933-01-1 (RAELP035) Lynx Number: RAELP035
860.1500	Residues in/on Field Corn and Sweet Corn (CG 15, 16)	48023726	Bayer CropScience (264)	OWN	M-364628-01-1 (RAELP053) Lynx Number: RAELP053
860.1500	Residues in/on Legume and Foliage of Legume (CG6, CG7) ex. Soybean	48023727	Bayer CropScience (264)	OWN	M-364821-01-1 (RAELP050) Lynx Number: RAELP050
860.1500	Residues in/on Soybean	48023728	Bayer CropScience (264)	OWN	M-364873-01-2 (RAELP052) Lynx Number: RAELP052
860.1500	Residues in/on Potato	48023729	Bayer CropScience (264)	OWN	M-364630-01-1 (RAELP047) Lynx Number: RAELP047
860.1500 SUPP	Residues in/on Potato (Germany, Northern France)	48023730	Bayer CropScience (264)	OWN	M-351871-01-2 (RA-2668/07) Lynx Number: RAEL001
860.1500 SUPP	Residues in/on Potato (Southern France, Spain)	48023731	Bayer CropScience (264)	OWN	M-351874-01-2 (RA-2670/07) Lynx Number: RAEL002

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DATA MATRIX

Date: March 31, 2010

EPA Reg. No./File Symbol:

Page 23 of 31

Applicant's/Registrant's Name & Address:

Bayer CropScience
Crop Protection Division
2 T.W. Alexander Drive
RTP, North Carolina 27709.

Product(s):
PENCLO 273.5FS

Ingredient: Penflufen, Clothianidin

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
860.1500 SUPP	Residues in/or Potato (France (North), Germany, Netherlands and UK)	48023732	Bayer CropScience (264)	OWN	M-356387-01-2 (08-2072) Lynx Number: RAEL006
860.1500 SUPP	Residues in/or Potato (France (South), Italy and Spain)	48023733	Bayer CropScience (264)	OWN	M-356466-01-2 (08-2200) Lynx Number: RAEL008
860.1520	Corn Processing, 5X - Seed Treatment (NAFTA)	48023734	Bayer CropScience (264)	OWN	M-364871-01-2 (RAELP054) Lynx Number: RAELP054
860.1520	Wheat Residue Trials (5X rate)	48023735	Bayer CropScience (264)	OWN	M-365262-01-1 (RAELP064) Lynx Number: RAELP064
860.1520	Soybean Residue Trials (5X rate)	48023736	Bayer CropScience (264)	OWN	M-364910-01-2 (RAELP065) Lynx Number: RAELP065
860.1520	Potato Processing (NAFTA)	48023737	Bayer CropScience (264)	OWN	M-364901-01-1 (RAELP044) Lynx Number: RAELP044
860.1850	Confined rotational crop (pyrazole label)	48023738	Bayer CropScience (264)	OWN	M-352773-01-2 (MEF-08/231) Lynx Number: MEELP015
860.1850	Confined rotational crop (phenyl label)	48023739	Bayer CropScience (264)	OWN	M-351315-01-2 (MEF-08/487) Lynx Number: MEELP016
860.1850	Confined rotational crop: determination of the TRR (phenyl and pyrazol	48023740	Bayer CropScience (264)	OWN	M-355594-01-2 (MEF-09/467) Lynx Number: MEELP058

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Date: March 31, 2010	EPA Reg. No./File Symbol:	Page 24 of 31
Applicant=s/Registrant=s Name & Address: Bayer CropScience Crop Protection Division 2 T.W. Alexander Drive RTP, North Carolina 27709.	Product(s): PENCLO 273.5FS	
Ingredient: Penflufen, Clothianidin		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
860.1900	Limited Rotational Crops - Wheat, Mustard Greens, Turnips	48023741	Bayer CropScience (264)	OWN	M-364937-01-1 (RAELP004) Lynx Number: RAELP004 Lynx Number: RAEL005 Lynx Number: RAELP066 Lynx Number: RAELP067 Lynx Number: RAELP068 Lynx Number: RAELP069
860.1900 SUPP	Rot. Crops - barley (winter), carrot, lettuce and wheat (DE)	48023742	Bayer CropScience (264)	OWN	M-361322-02-2 (08-2500) Lynx Number: RAEL010
860.1900 SUPP	Rot. Crops barley (spring), barley (winter), carrot and lettuce (FR)	48023743	Bayer CropScience (264)	OWN	M-361328-01-2 (08-2501) Lynx Number: RAEL011
860.1900 SUPP	Rot. Crops barley (spring), barley (winter), carrot and lettuce (UK)	48023744	Bayer CropScience (264)	OWN	M-361331-01-2 (08-2502) Lynx Number: RAEL012
860.SUPP	Method for air (enforcement)	48023745	Bayer CropScience (264)	OWN	M-349742-01-2 (P605097530) Lynx Number: RAELP032
860.SUPP	PEC calculation package (soil, sed, sw, gw, air) at the end of project	48023746	Bayer CropScience (264)	OWN	M-358596-01-2 (MEF-09/689) Lynx Number: MEELP086
860.SUPP	Aqueous hydrolysis under conditions of processing studies	48023747	Bayer CropScience (264)	OWN	M-310296-01-2 (MEF-08/186) Lynx Number: MEELP042
860.SUPP	Aqueous hydrolysis under conditions of proc. studies (3-hydroxy-butyl)	48023748	Bayer CropScience (264)	OWN	M-350351-01-2 (MEF-08/446) Lynx Number: MEELP088

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Date: March 31, 2010

EPA Reg. No./File Symbol:

Page 25 of 31

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Bayer CropScience
Crop Protection Division
2 T.W. Alexander Drive
RTP, North Carolina 27709.

Product(s):

PENCLO 273.5FS

Ingredient: Penflufen, Clothianidin

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870 Health Effects Guidelines					
870.1100	Acute Oral Toxicity	48023749	Bayer CropScience (264)	OWN	M-294194-01-2 (AT04001) Lynx Number: TXELP005
870.1200	Acute Dermal Toxicity	48023750	Bayer CropScience (264)	OWN	M-294249-01-2 (AT04068) Lynx Number: TXELP007
870.1300	Acute Inhalation Toxicity	48023801	Bayer CropScience (264)	OWN	M-295831-02-2 (AT04380) Lynx Number: TXELP010
870.2400	Acute Eye Irritation	48023802	Bayer CropScience (264)	OWN	M-293657-01-2 (AT04158) Lynx Number: TXELP025
870.2500	Acute Dermal Irritation	48023803	Bayer CropScience (264)	OWN	M-293630-01-2 (AT04149) Lynx Number: TXELP026
870.2600	Skin Sensitization	48023804	Bayer CropScience (264)	OWN	M-290842-02-2 (AT03941) Lynx Number: TXELP006
870.3100	90-day Oral Toxicity in rat	48023805	Bayer CropScience (264)	OWN	M-273186-01-2 (SA 04199) Lynx Number: TXELX001
870.3100	90-day Oral Toxicity in rat - complementary study	48023806	Bayer CropScience (264)	OWN	M-273644-01-2 (SA05148) Lynx Number: TXELX012 Lynx Number: TXELX010
870.3100	90-day Oral Toxicity in mouse	48023807	Bayer CropScience (264)	OWN	M-309584-01-2 (SA 05029) Lynx Number: TXELX006

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Date: March 31, 2010	EPA Reg. No./File Symbol:	Page 26 of 31
Applicant=s/Registrant=s Name & Address: Bayer CropScience Crop Protection Division 2 T.W. Alexander Drive RTP, North Carolina 27709.	Product(s): PENCLO 273.5FS	
Ingredient: Penflufen, Clothianidin		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.3150	90-day Oral Toxicity in Nonrodents	48023808	Bayer CropScience (264)	OWN	M-298785-01-2 (SA 06327) Lynx Number: TXELP004
870.3200	21/28-Day Dermal Toxicity	48023809	Bayer CropScience (264)	OWN	M-352352-01-1 (202021) Lynx Number: TXELP044
870.3700	Prenatal Developmental Toxicity Study (rat)	48023810	Bayer CropScience (264)	OWN	M-307168-01-3 (SA 06329) Lynx Number: TXELP017
870.3700	Prenatal Developmental Toxicity Study (rabbit)	48023811	Bayer CropScience (264)	OWN	M-307955-01-2 (SA 06330) Lynx Number: TXELP019
870.3800	Reproduction and Fertility Effects	48023812	Bayer CropScience (264)	OWN	M-357261-01-1 (07-R72-MK) Lynx Number: TXELP021
870.4100	Chronic Toxicity	48023813	Bayer CropScience (264)	OWN	M-349926-01-2 (SA 06328) Lynx Number: TXELP022
870.4200	Carcinogenicity	48023814	Bayer CropScience (264)	OWN	M-357859-01-2 (SA 06326) Lynx Number: TXELP024
870.4300	Combined Chronic Toxicity/Carcinogenicity	48023815	Bayer CropScience (264)	OWN	M-357848-01-2 (SA 06115) Lynx Number: TXELP003
870.5100	Salmonella/microsome test	48023816	Bayer CropScience (264)	OWN	M-295834-01-2 (AT04290) Lynx Number: TXELP008
870.5100	Salmonella typhimurium reverse mutation assay	48023817	Bayer CropScience (264)	OWN	M-355090-01-2 (1271801) Lynx Number: TXELP062

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DATA MATRIX

Date: March 31, 2010	EPA Reg. No./File Symbol:	Page 27 of 31
Applicant's/Registrant's Name & Address: Bayer CropScience Crop Protection Division 2 T.W. Alexander Drive RTP, North Carolina 27709.	Product(s): PENCLO 273.5FS	
Ingredient: Penflufen, Clothianidin		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.5100	Salmonella/microsome test (3-hydroxy-butyl)	48023818	Bayer CropScience (264)	OWN	M-306566-01-2 (AT04777) Lynx Number: TXELP042
870.5100	Salmonella/microsome test (pyrazolyl-AAP)	48023819	Bayer CropScience (264)	OWN	M-349984-01-2 (AT05286) Lynx Number: TXELP110
870.5300	V79/HPRT test in vitro	48023820	Bayer CropScience (264)	OWN	M-295851-01-2 (AT04328) Lynx Number: TXELP009
870.5300	V79/HPRT test in vitro (supplementary)	48023821	Bayer CropScience (264)	OWN	M-358056-01-2 (1271802) Lynx Number: TXELP063
870.5300	V79/HPRT test in vitro (3-hydroxy-butyl)	48023822	Bayer CropScience (264)	OWN	M-302723-01-2 (AT04610) Lynx Number: TXELP043
870.5300	V79/HPRT test in vitro (pyrazolyl-AAP)	48023823	Bayer CropScience (264)	OWN	M-355623-01-2 (AT05453) Lynx Number: TXELP111
870.5375	In vitro chromosome aberration test	48023824	Bayer CropScience (264)	OWN	M-294392-01-2 (AT04201) Lynx Number: TXELP011
870.5375	In vitro chromosome aberration test (supplementary)	48023825	Bayer CropScience (264)	OWN	M-355092-01-2 (1271803) Lynx Number: TXELP063 Lynx Number: TXELP064
870.5375	In vitro chromosome aberration test (3-hydroxy-butyl)	48023826	Bayer CropScience (264)	OWN	M-304932-01-2 (AT04638) Lynx Number: TXELP038

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DATA MATRIX

Date: March 31, 2010	EPA Reg. No./File Symbol:	Page 28 of 31
Applicant=s/Registrant=s Name & Address: Bayer CropScience Crop Protection Division 2 T.W. Alexander Drive RTP, North Carolina 27709.	Product(s): PENCLO 273.5FS	
Ingredient: Penflufen, Clothianidin		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.5375	In vitro chromosome aberration test (pyrazolyl-AAP)	48023827	Bayer CropScience (264)	OWN	M-356328-01-2 (AT05509) Lynx Number: TXELP109
870.5395	Mammalian Erythrocyte Micronucleus Test	48023828	Bayer CropScience (264)	OWN	M-299229-01-2 (AT04397) Lynx Number: TXELP012
870.6200	Acute oral neurotoxicity screening study	48023829	Bayer CropScience (264)	OWN	M-328497-01-1 (201967) Lynx Number: TXELP016
870.6200	Subchronic neurotoxicity screening study	48023830	Bayer CropScience (264)	OWN	M-328503-01-1 (201961) Lynx Number: TXELP020
870.7485	[Phenyl-UL-13C6/14C] Metabolism in the rat	48023831	Bayer CropScience (264)	OWN	M-352042-01-2 (MEF-08/175) Lynx Number: MEELP009
870.7485	[Pyrazole-3-14C] Metabolism in the rat	48023832	Bayer CropScience (264)	OWN	M-348815-01-2 (MEF-08/176) Lynx Number: MEELP033
870.7485	[Phenyl-UL-13C6/14C] Quantitative whole body autoradiography	48023833	Bayer CropScience (264)	OWN	M-345178-01-2 (MEF-08/162) Lynx Number: MEELX003
870.7485	[Pyrazole-3-14C] Quantitative whole body autoradiography	48023834	Bayer CropScience (264)	OWN	M-344803-01-2 (MEF-08/179) Lynx Number: MEELP003
870.7485	[Phenyl-UL-13C6/14C] Metabolism in organs and tissues	48023835	Bayer CropScience (264)	OWN	M-354487-01-2 (MEF-09/475) Lynx Number: MEELP052
870.7485	[Pyrazole-3-14C] (BYF14182-3-hydroxy-butyl) Metabolism in the rat	48023836	Bayer CropScience (264)	OWN	M-354679-01-2 (MEF-09/376) Lynx Number: MEELP099

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DATA MATRIX

Date: March 31, 2010	EPA Reg. No./File Symbol:	Page 29 of 31
Applicant's/Registrant's Name & Address: Bayer CropScience Crop Protection Division 2 T.W. Alexander Drive RTP, North Carolina 27709.	Product(s): PENCLO 273.5FS	
Ingredient: Penflufen, Clothianidin		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.7800	Immunotoxicity	48023837	Bayer CropScience (264)	OWN	M-307722-01-2 (AT04807) Lynx Number: TXELP029
870.SUPP	Exploratory 28-day toxicity study in the rat	48023838	Bayer CropScience (264)	OWN	M-080714-01-2 (SA 03339) Lynx Number: TXSDX004
870.SUPP	Preliminary 28-day toxicity study in the mouse	48023839	Bayer CropScience (264)	OWN	M-253176-01-2 (SA04191) Lynx Number: TXELX005
870.SUPP	Preliminary 28-day toxicity study in the dog	48023840	Bayer CropScience (264)	OWN	M-256713-01-2 (SA04300) Lynx Number: TXELX003
SUPP Supplemental Information					
SUPP	Possible development of resistance or cross-resistance	48023841	Bayer CropScience (264)	OWN	M-358376-01-2 (MHA PEN-01/2009)
SUPP	Mode of action	48023842	Bayer CropScience (264)	OWN	M-359100-03-2 (2009-12-03 -Penflufen)
SUPP	Biological activity of the enantiomers	48023843	Bayer CropScience (264)	OWN	M-359242-01-2 (M-359242-01-2)
SUPP	Document C (Labels)	48023844	Bayer CropScience (264)	OWN	M-365586-01-1 (M-365586-01-1)
SUPP	Document D1 (Intended uses (EU))	48023845	Bayer CropScience (264)	OWN	M-364935-01-1 (M-364935-01-1)
SUPP	Document D1 (Intended uses (NAFTA))	48023846	Bayer CropScience (264)	OWN	M-364934-01-1 (M-364934-01-1)
SUPP	Document J - Confidential data and information	48023847	Bayer CropScience (264)	OWN	M-365677-01-1 (US0027)
SUPP	Tier 2 summary of the identity of the active substance	48023848	Bayer CropScience (264)	OWN	M-365036-01-1 (G202168)

Signature 	Name and Title: Jamin Huang	Date: March 31, 2010
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EPA Form 8750-35 (12-2003) Electronic Paper versions available. Submit only Paper version.

Agency Internal Use Copy



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060; 2070-0057;
2070-0107; 2070-0122; 2070-01634

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for Reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, Collection Strategies Division (2822T), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: March 31, 2010	EPA Reg. No./File Symbol:	Page 30 of 31
Applicant=s/Registrant=s Name & Address: Bayer CropScience Crop Protection Division 2 T.W. Alexander Drive RTP, North Carolina 27709.	Product(s): PENCLO 273.5FS	
Ingredient: Penflufen, Clothianidin		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
SUPP	Tier 2 summary of physical and chemical properties	48023849	Bayer CropScience (264)	OWN	M-365034-01-1 (G202167)
SUPP	Tier 2 summary of further information of the active substance	48023850	Bayer CropScience (264)	OWN	M-365535-01-1 (US0018)
SUPP	Tier 2 Proposals for classification and labelling	48023901	Bayer CropScience (264)	OWN	M-365532-01-1 (US0019)
SUPP	Tier 2 summary of the analytical methods and validation	48023902	Bayer CropScience (264)	OWN	M-365663-01-1 (US0020)
SUPP	Tier 2 summary of the toxicological and toxicokinetic studies	48023903	Bayer CropScience (264)	OWN	M-364889-01-1 (G202165) Lynx Number: G202165
SUPP	Tier 2 summary of the metabolism and residues data	48023904	Bayer CropScience (264)	OWN	M-365669-01-1 (US0025)
SUPP	Tier 2 summary of fate and behaviour in the environment	48023905	Bayer CropScience (264)	OWN	M-365670-01-1 (US0026)
SUPP	Tier 2 summary of the ecotoxicological studies	48023906	Bayer CropScience (264)	OWN	M-364886-01-1 (EBELP081) Lynx Number: EBELP081
SUPP	Drinking water exposure assessment - USA	48023907	Bayer CropScience (264)	OWN	M-365186-01-1 (MEELP069) Lynx Number: MEELP069
SUPP	Drinking water exposure assessment - Canada	48023908	Bayer CropScience (264)	OWN	M-365189-01-1 (MEELP076) Lynx Number: MEELP076
SUPP	Dietary (food and water) risk assessment - USA	48023909	Bayer CropScience (264)	OWN	M-365279-01-1 (G202157)
SUPP	Dietary (food and water) risk assessment - Canada	48023910	Bayer CropScience (264)	OWN	M-365263-01-1 (G202158)
SUPP	Mixer/loader/appliator Risk Assessment - USA	48023911	Bayer CropScience (264)	OWN	M-365264-01-1 (G202159)
SUPP	Mixer/loader/appliator Risk Assessment - Canada	48023912	Bayer CropScience (264)	OWN	M-365265-01-1 (G202160)

Signature	Name and Title: Jamin Huang	Date: March 31, 2010
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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060; 2070-0057;
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Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for Reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, Collection Strategies Division (2822T), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: March 31, 2010

EPA Reg. No./File Symbol:

Page 31 of 31

Applicant's/Registrant's Name & Address:

Bayer CropScience
Crop Protection Division
2 T.W. Alexander Drive
RTP, North Carolina 27709.

Product(s):
PENCLO 273.5FS

Ingredient: Penflufen, Clothianidin

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
SUPP	Ecological risk assessment - USA and Canada	48023913	Bayer CropScience (264)	OWN	M-365433-01-1 (EBELL002) Lynx Number: EBELL002
SUPP	Environmental Exposure Assessment - US	48023914	Bayer CropScience (264)	OWN	M-365191-01-1 (MEELP077) Lynx Number: MEELP077
SUPP	Environmental Exposure Assessment - Canada	48023915	Bayer CropScience (264)	OWN	M-365192-01-1 (MEELP077CA) Lynx Number: MEELP077
SUPP	HED Overview Document	48023916	Bayer CropScience (264)	OWN	M-365683-01-1 (US0016)
SUPP	MRL Document	48023917	Bayer CropScience (264)	OWN	M-365428-02-1 (G202170)
SUPP	Document N - List of metabolites	48023918	Bayer CropScience (264)	OWN	M-365676-01-1 (US0024)
SUPP	Document N - List of end points	48023919	Bayer CropScience (264)	OWN	M-365685-01-1 (US0029)
SUPP	Tier 3 summary - Overall summary and assessment	48023920	Bayer CropScience (264)	OWN	M-365686-01-1 (US0030)

Signature

Name and Title:
Jamin Huang

Date: March 31, 2010

PENCLO 273.5FS

For use as a fungicide and insecticide cotton seed and potato seed piece dressing, designed to protect against certain disease and insect pests.

ACTIVE INGREDIENT:

Penflufen6.0%
Clothianidin18.6%

OTHER INGREDIENTS:75.4%
TOTAL 100.0%

Contains 1.72 lb Clothianidin and 0.56 lb Penflufen per gallon (206.5 g Clothianidin and 66.6 g Penflufen per liter)

EPA Reg. No. 264-XXXX

EPA Est.

KEEP OUT OF REACH OF CHILDREN CAUTION

For MEDICAL And TRANSPORTATION Emergencies ONLY Call 24 Hours A Day 1-800-334-7577
For PRODUCT USE Information Call 1-866-99BAYER (1-866-992-2937)

FIRST AID

IF SWALLOWED:	<ul style="list-style-type: none">• Call a poison control center or doctor immediately for treatment advice.• Have person sip a glass of water if able to swallow.• Do not induce vomiting unless told to do so by a poison control center or doctor.• Do not give anything by mouth to an unconscious person.
IF ON SKIN	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15-20 minutes.• Call a poison control center or doctor for treatment advice.
IF INHALED:	<ul style="list-style-type: none">• Move person to fresh air.• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible.• Call a poison control center or doctor for further treatment advice.
IF IN EYES:	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15-20 minutes.• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.• Call a poison control center or doctor for treatment advice.
In case of emergency call toll free the Bayer CropScience Emergency Response Telephone No. 1-800-334-7577. Have a product container or label with you when calling a poison control center or doctor, or going for treatment.	

PRECAUTIONARY STATEMENTS

CAUTION

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

Harmful if swallowed or absorbed through the skin. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove contaminated clothing and wash before reuse.



M-365404-01-1

E-SUBMISSION

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Some materials that are chemical-resistant to this product are barrier laminate, nitrile rubber, neoprene rubber. If you want more options, follow the instructions for category C on an EPA chemical-resistance category selection chart.

All mixers, loaders, applicators and other handlers must wear:

- long sleeved shirt and long pants,
- socks plus shoes,
- chemical resistant gloves, except when bagging or sewing bags of treated seeds,

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry.

USER SAFETY RECOMMENDATIONS

Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.

Remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS

Do not contaminate water when disposing of equipment washwater or rinsate.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Not for direct application to seeds in a hopper-box, planter-box, or slurry-box.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage, disposal or cleaning of equipment.

PESTICIDE STORAGE

Store in original container away from feed and food. Store in cool, dry area. Do not store in direct sunlight. Do not allow prolonged storage in temperatures that exceed 105°F (40°C) or in temperatures that fall below 14°F (-10°C).

PESTICIDE DISPOSAL

Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

CONTAINER DISPOSAL

Rigid, Non-refillable containers small enough to shake (i.e., with capacities equal to or less than 5 gallons)

Non-refillable container. Do not reuse or refill this container. Offer for recycling, if available. Triple rinse or pressure rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container 1/4 full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times.

Once container is rinsed, offer for recycling if available or puncture and dispose of in a sanitary landfill or if allowed by State and local authorities by burning. If burned stay out of smoke.

Rigid Non-refillable containers that are too large to shake (i.e., with capacities greater than 5 gallons or 50 lbs)

Non-refillable Containers

Non-refillable containers - Do not reuse or refill this container. Refer to Bottom Discharge IBC or Top Discharge IBC, Drums, Kegs information as follows.

Bottom Discharge IBC (e.g. - Schuetz Caged IBC or Snyder Square Stackable)

Pressure rinsing the container before final disposal is the responsibility of the person disposing of the container. To pressure rinse the container before final disposal, empty the remaining contents from the IBC into application equipment or mix tank. Raise the bottom of the IBC by 1.5 inches on the side which is opposite of the bottom discharge valve to promote more complete product removal.

Completely remove the top lid of the IBC. Use water pressurized to at least 40 PSI to rinse all interior portions. Continuously pump or drain rinsate into application equipment or rinsate collection system while pressure rinsing. Continue pressure rinsing for 2 minutes or until rinsate becomes clear. Replace the lid and close bottom valve.

Top Discharge IBC, Drums, Kegs (e.g.— Snyder 120 Next Gen, Bonar B120, Drums, Kegs).

Triple rinsing the container before final disposal is the responsibility of the person disposing of the container. To triple rinse the container before final disposal, empty the remaining contents from this container into application equipment or mix tank. Fill the container at least 10 percent full with water. Agitate vigorously or recirculate water with the pump for 2 minutes. Rinse all interior surfaces. Pour or pump rinsate into application equipment or rinsate collection system. Repeat this procedure two more times.

Once container is rinsed, offer for recycling if available or puncture and dispose of in a sanitary landfill.

Refillable Containers

Refillable container — Refer to Bottom Discharge IBC or Top Discharge IBC, Drums, Kegs information as follows. Refill this container with pesticide only. Do not reuse this container for any other purpose. Contact your Ag retailer or Bayer CropScience for container return, disposal and recycling information.

Bottom Discharge IBC (e.g. — Schuetz Caged IBC or Snyder Square Stackable)

Pressure rinsing the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. To pressure rinse the container before final disposal, empty the remaining contents from the IBC into application equipment or mix tank. Raise the bottom of the IBC by 1.5 inches on the side which is opposite of the bottom discharge valve to promote more complete product removal. Completely remove the top lid of the IBC. Use water pressurized to at least 40 PSI to rinse all interior portions. Continuously pump or drain rinsate into application equipment or rinsate collection system while pressure rinsing. Continue pressure rinsing for 2 minutes or until rinsate becomes clear. Replace the lid and close bottom valve.

Top Discharge IBC, Drums, Kegs (e.g.— Snyder 120 Next Gen, Bonar B120, Drums, Kegs).

Triple rinsing the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. To triple rinse the containers before final disposal, empty the remaining contents from this container into application equipment or mix tank. Fill the container at least 10 percent full with water. Agitate vigorously or recirculate water with the pump for 2 minutes. Rinse all interior surfaces. Pour or pump rinsate into application equipment or rinsate collection system. Repeat this procedure two more times.

Once container is rinsed, offer for recycling if available or puncture and dispose of in a sanitary landfill.

LABELING OF TREATED SEED

Federal law requires that bags containing treated seeds shall be labeled with the following information:

"This seed has been treated with Penflufen and Clothianidin. Do not use for feed, food or oil purposes. Store away from feeds and foodstuffs. When opening this bag or loading/pouring the treated seed, wear long-sleeved shirt, long pants, shoes, socks, and chemical resistant gloves."

GENERAL INFORMATION

PENCLO 273.5FS is a fungicide and insecticide for use on cotton seed and potato seed pieces designed to protect against certain disease and insect pests.

CROP ROTATION

Crops on this label, and other crops for which tolerances exist for clothianidin and penflufen may be replanted at any time. Grasses, non-grass animal feeds, dried beans and dried peas may be planted after 30 days. Do not plant any other crop in the treated area for at least twelve months after treated seeds are planted.

CROP	PEST	APPLICATION RATE	DIRECTIONS
<p>Potato (seed piece application)</p>	<p>Black scurf, stem & stolon canker, caused by seedborne and soilborne (suppression) <i>Rhizoctonia solani</i></p> <p>Silver scurf caused by seed borne <i>Helminthosporium solani</i> (suppression)</p> <p>Colorado potato beetle</p> <p>Aphids</p> <p>Leafhopper</p> <p>Potato flea beetle</p> <p>Wireworm (reduction of seed piece damage)</p>	<p>SEED PIECE TREATMENT:</p> <p>Apply 0.47 fl oz per 100 lbs of seed pieces</p>	<p>For optimal disease control, good coverage of the seed piece is required.</p> <p>Apply specified dosage as a diluted spray using equipment that ensures uniform coverage of each seed piece. Apply no more than 2.5 fl oz of slurry/100 lbs of seed pieces. Apply only in areas with adequate ventilation or in areas that are equipped to remove spray mist or dust.</p> <p>As part of the seed cutting and treating process, application of an inert absorbent ingredient is recommended to improve suberization. For added <i>Fusarium</i> protection apply a Mancozeb containing product specifically designed for application to potatoes in place of the inert absorbent.</p> <p>Do not use treated seed pieces for food, feed, or fodder.</p> <p>For best control of soilborne black scurf, apply PEN 240FS or PENRED 240 FS as an in-furrow spray in addition to the seed piece application. See the PEN 240FS or PENRED 240 FS label for in-furrow use instructions.</p>
<p>Cotton</p>	<p>Seed rot and damping-off caused by <i>Rhizoctonia solani</i></p> <p>Thrips (suppression)</p>	<p>RATE PER 100 LBS OF SEED:</p> <p>Apply 2.31 fl oz per 100 lbs seed</p>	<p>Apply using standard slurry or mist-type seed treatment equipment. Uniform application of seed is necessary to ensure seed safety and best disease protection. Product should be diluted with sufficient water to ensure complete seed coverage. Consult a seed treatment specialist regarding slurry rates recommended for the crop to be treated with PEN 240FS. For best results, use high quality, properly cleaned seed.</p> <p>This product does not contain colorant. The purchaser of this product is responsible for ensuring that all seed treated with this product are adequately dyed with a suitable color to prevent its accidental use as food for man or feed for animals. Refer to 21CFR, part 2.25. Any colorant added to treated seed must be cleared for use under 40CFR, Part 153.155.</p>

Refillable Containers

End users are authorized to remove tamper evident cables as required to remove the product from the container unless the container is equipped with one way valves and refilling or returning is planned. If this is the case, end users are not authorized to remove tamper evident cables, one way valves or clean container. See Container Disposal instructions under Storage and Disposal.

IMPORTANT: READ BEFORE USE

Read the entire Directions for Use, Conditions, Disclaimer of Warranties and Limitations of Liability before using this product. If terms are not acceptable, return the unopened product container at once.

By using this product, user or buyer accepts the following Conditions, disclaimer of Warranties and Limitations of Liability.

Treatment of highly mechanically damaged seed, or seed of known low vigor and poor quality, may result in reduced germination and/or reduction of seed and seedling vigor. Treat and conduct germination tests on a small portion of seed before committing the total seed lot to a selected chemical treatment. Due to seed quality conditions beyond the control of Bayer CropScience, no claims are made to guarantee germination of carry-over seed.

CONDITIONS: The directions for use of this product are believed to be adequate and must be followed carefully. However, it is impossible to eliminate all risks associated with the use of this product. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as weather conditions, presence of other materials, or the manner of use or application, all of which are beyond the control of Bayer CropScience. All such risks shall be assumed by the user or buyer.

DISCLAIMER OF WARRANTIES: TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BAYER CROPSCIENCE MAKES NO WARRANTIES, EXPRESS OR IMPLIED, OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE OR OTHERWISE, THAT EXTEND BEYOND THE STATEMENTS MADE ON THIS LABEL. No agent of Bayer CropScience is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BAYER CROPSCIENCE DISCLAIMS ANY LIABILITY WHATSOEVER FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT.

LIMITATIONS OF LIABILITY: TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER FOR ANY AND ALL LOSSES, INJURIES OR DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, WHETHER IN CONTRACT, WARRANTY, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE, SHALL NOT EXCEED THE PURCHASE PRICE PAID, OR AT BAYER CROPSCIENCE'S ELECTION, THE REPLACEMENT OF PRODUCT.

NOTICE TO BUYER

Purchase of this material does not confer any rights under patents governing this product or the use thereof in countries outside of the United States.

NET CONTENTS:

PRODUCED FOR



Bayer CropScience

**Bayer CropScience LP
P.O. Box 12014, 2 T.W. Alexander Drive
Research Triangle Park, North Carolina 27709
1-866-99BAYER (1-866-992-2937)**

PENCLO 273.5FS (PENDING) 3/31/10

INERT INGREDIENT STATUS FORM

Reviewer Name: Alganesh Debesai			Request date: 4/12/2010
Tel: 703-308-8353	RD/IIAB	CUBE: S-7954	

A. COMMENTS:

Inert Ingredients not currently approved. See below for details.

B. PESTICIDE PRODUCT INFORMATION:

Receipt Number: EPA Reg. No/File Symbol:	Date on CSF: 2/23/2010	Food-Use Pesticide: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
Product Name: PENCLO 273.5FS	Formulation: BASIC	

C. INGREDIENT INFORMATION:

Tolerance Exemption(s)¹

Ingredient No.1

	910	920	930	940	950	960
Chem. Name:						
Trade Name:						
CAS Reg. No.:						
Comments: The Agency does not have the composition of this trade name product on file and therefore cannot verify the identity of the components(s). Full composition from the manufacturer of the trade name product is needed to verify and review the component(s) for inert approval. The manufacturer may submit the compositional directly to the Agency. Compositional information needs to be on the manufacturer's company letterhead and should include the full product name and chemical name, CAS Reg. No. and %w/w of each component – components must total 100%.						

Ingredient No. 2

	910	920	930	940	950	960
Chem. Name:						
Trade Name:						
CAS Reg. No.:						
Comments: The Agency does not have the composition of this trade name product on file and therefore cannot verify the identity of the components(s). Full composition from the manufacturer of the trade name product is needed to verify and review the component(s) for inert approval. The manufacturer may submit the compositional directly to the Agency. Compositional information needs to be on the manufacturer's company letterhead and should include the full product name and chemical name, CAS Reg. No. and %w/w of each component – components must total 100%.						

Completed By: Alganesh Debesai

Date Completed: 4/15/10

¹Language from the Code of Federal Regulations (40 CFR 180, subpart D):

40 CFR 180.910: Inert ingredients used pre- and post-harvest; 40 CFR 180.920: Inert ingredients used pre-harvest; 40 CFR 180.930: Inert ingredients applied to animals; 40 CFR 180.940: Tolerance exemptions for active and inert ingredients for use in antimicrobial formulations; 40 CFR 180.950: Tolerance exemptions for minimal risk active and inert ingredients; and 40 CFR 180.960: Polymers.

CHEMICAL NAME/PESTICIDE CHEMICAL CODE (PCC)

REQUEST FORM

CR# 10-137

REQUESTOR NAME: <u>Megafacta</u>		Request date: <u>4/13/10</u>	
Tel: <u>305-6471</u>	ORG: <u></u>	CUBE: <u>6941</u>	MAIL CODE: <u></u>

CSF ATTACHED:

- ☒ YES If CSF is attached complete Item A and the chemical name in item C.
☐ NO If CSF is not attached complete Item A through C.

A. INFORMATION REQUIRED:

- ☐ Check Applicable Category
☒ Provide PCC and Tolerance Exemption Status For Food-Use Inert ingredient (s).
☐ Provide PCC for Non-Food Use inert Ingredient (s).
☐ Provide PCC for Active Ingredient (s).
☐ Provide PCC for Dye.
☐ Determine if Fragrance is Acceptable for Use In Formulation.
☐ Other (Describe):

B. PESTICIDE PRODUCT INFORMATION:

EPA Reg. No/File Symbol: <u>264-RREL</u>	Product Name: <u>Pendo 273.5 FS</u>
Registrant: <u>Bayer CropScience</u>	Food-Use Pesticide: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
Percent in Formulation: <u></u>	PM No.: <u></u>

C. INGREDIENT INFORMATION:

Ingredient No.1

INFORMATION REPORTED:

Chem. Name: <u>[REDACTED]</u>	PCC: <u></u>
Trade Name: <u>[REDACTED]</u>	TOL STATUS: <u></u>
CAS Reg. No.: <u>[REDACTED]</u>	OTHER INF.: <u>Need more by</u>
MRID Nos.: <u></u>	<u>See inert status form</u>

Ingredient No.2:

Chem. Name: <u>[REDACTED]</u>	PCC: <u></u>
Trade Name: <u>[REDACTED]</u>	TOL STATUS: <u></u>
CAS Reg. No.: <u>[REDACTED]</u>	OTHER INF.: <u>Need more</u>
MRID Nos.: <u>Is the trade name same as</u>	<u>present</u>
<u>under PC code</u>	<u>[REDACTED]</u>

Completed By: Algonesh Oshosi
Date Completed: 4/15/10

CHEMICAL NAME/PESTICIDE CHEMICAL CODE (PCC)

REQUEST FORM

CR# _____

REQUESTOR NAME:			Request date:
Tel:	ORG.:	CUBE:	MAIL CODE:

CSF ATTACHED:

- ☐ YES If CSF is attached complete Item A and the chemical name in item C.
☐ NO If CSF is not attached complete Item A through C.

A. INFORMATION REQUIRED:

- ☒ Check Applicable Category
☐ Provide PCC and Tolerance Exemption Status For Food-Use Inert ingredient (s).
☐ Provide PCC for Non-Food Use inert Ingredient (s).
☐ Provide PCC for Active Ingredient (s).
☐ Provide PCC for Dye.
☐ Determine if Fragrance is Acceptable for Use in Formulation.
☐ Other (Describe): _____

B. PESTICIDE PRODUCT INFORMATION:

EPA Reg. No/File Symbol:	Product Name:
Registrant:	Food-Use Pesticide: <input type="checkbox"/> Yes <input type="checkbox"/> No
Percent in Formulation :	PM No.:

C. INGREDIENT INFORMATION:

Ingredient No.1

INFORMATION REPORTED:

Chem. Name:	PCC:
Trade Name:	TOL. STATUS:
CAS Reg. No.:	OTHER INF.:
MRID Nos.:	
Comments refer to Y2K. Approved for food use?	

Ingredient No.2:

Chem. Name:	PCC:
Trade Name:	TOL. STATUS:
CAS Reg. No.:	OTHER INF.:
MRID Nos.:	

Completed By: _____
 Date Completed: _____

Inert ingredient information may be entitled to confidential treatment